

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**OREGON DID NOT BILL
MANUFACTURERS FOR REBATES FOR
PHYSICIAN-ADMINISTERED 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

March 2015
A-09-13-02037

Office of Inspector General

<http://oig.hhs.gov>

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

Office of Audit Services

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

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at <http://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.

EXECUTIVE SUMMARY

During 2010, Oregon did not bill manufacturers for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Oregon did not collect an estimated \$1.9 million (Federal share) in rebates.

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 the rebates to reduce the cost of the drugs to the program. However, previous Office of Inspector General reviews found that States did not always bill and collect all rebates due for drugs administered by physicians. In one of those reviews, which focused on fee-for-service claims, we found that Oregon claimed unallowable Federal Medicaid reimbursement by not billing manufacturers for rebates for some physician-administered drugs. This review covers physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Oregon.

Our objective was to determine whether the Oregon Health Authority, Division of Medical Assistance Programs (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement with 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.

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. Physician-administered drugs may be covered by the capitation payment. To claim Federal reimbursement, States report to CMS the 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 physician-administered drugs). States must report drug rebates on the Form CMS-64.

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for the drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to bill and collect rebates.

Effective March 23, 2010, the Patient Protection and Affordable Care Act requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs 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. Physician-administered drugs dispensed to enrollees of MCOs are recorded in MCO drug utilization data.

In Oregon, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with a contractor to manage its drug rebate program. In calendar year 2010, Oregon paid MCOs approximately \$1.8 billion (\$1.3 billion Federal share), which included expenditures for physician-administered drugs. Our audit covered the State agency's MCO payments and MCO drug utilization data for physician-administered drugs from April through December 2010 (audit period).

WHAT WE FOUND

During our audit period, the State agency did not comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not have NDCs for drug utilization data submitted by MCOs for physician-administered drugs, and the State agency did not bill manufacturers for rebates for these drugs. The State agency estimated that it paid \$11,275,385 (\$7,078,720 Federal share) to MCOs for physician-administered drugs, an estimate we determined to be reasonable. On the basis of this amount, the State agency estimated that it did not collect rebates of \$3,049,462 (\$1,914,462 Federal share), an estimate we also determined to be reasonable.

The State agency did not bill manufacturers for rebates because the State agency's Medicaid Management Information System did not have an edit during our audit period to ensure that NDCs were present and valid in the MCO drug utilization data for physician-administered drugs. The State agency informed us that it implemented NDC edits on July 1, 2011. The State agency also informed us that in December 2012, it retroactively billed for and collected from manufacturers rebates for physician-administered drugs dispensed through MCOs and paid since July 1, 2011. Although State regulations and guidance required MCOs to submit NDCs for physician-administered drugs, the State agency did not ensure that MCOs submitted NDCs.

WHAT WE RECOMMEND

We recommend that the State agency:

- bill for and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs during our audit period and refund to the Federal Government the estimated \$1,914,462 Federal share,
- bill for and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs from January 1 through June 30, 2011, and refund the Federal share of the rebates collected,

- verify that the NDC edits (implemented on July 1, 2011) ensure that NDCs are present and valid in all drug utilization data, and
- ensure that MCOs submit drug utilization data containing NDCs for physician-administered drugs.

STATE AGENCY COMMENTS

The State agency concurred with all of our recommendations and described corrective actions that it had taken or planned to take.

TABLE OF CONTENTS

INTRODUCTION	1
Why We Did This Review	1
Objective	1
Background	1
Medicaid Drug Rebate Program	1
Federal Reimbursement to States for Payments to Medicaid Managed-Care Organizations	2
Rebates for Physician-Administered Drugs	2
The State Agency’s Medicaid Drug Rebate Program	3
How We Conducted This Review	3
FINDING	3
Federal and State Requirements	4
The State Agency Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	4
RECOMMENDATIONS	5
STATE AGENCY COMMENTS	5
APPENDIXES	
A: Related Office of Inspector General Reports	6
B: Audit Scope and Methodology	7
C: Federal and State Requirements Related to Physician-Administered Drugs	9
D: State Agency Comments	11

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 States. States bill the manufacturers for the 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. In one of those reviews, which focused on fee-for-service claims, we found that Oregon claimed unallowable Federal Medicaid reimbursement by not billing manufacturers for rebates for some physician-administered drugs.¹ This review covers physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Oregon. Appendix A lists previous OIG reviews of the Medicaid drug rebate program.

OBJECTIVE

Our objective was to determine whether the Oregon Health Authority, Division of Medical Assistance Programs (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement with 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.

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.² 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 National Drug Code (NDC), unit type, units per package size, and product name.

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary to bill manufacturers for rebates as described in section 1927(a)(7) of the

¹ *Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs* (A-09-12-02080), issued April 2014.

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

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

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

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 individual receiving services regardless of whether the enrollee receives services during the relevant time period (42 CFR § 438.2). Physician-administered drugs may be covered by the capitation payment.

To claim Federal reimbursement, States report capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (Form CMS-64). These expenditures are not identified by specific type of service (such as physician-administered drugs). States must report decreasing adjustments to drug expenditures and drug rebates on the Form CMS-64. States report drug rebate accounts receivable data on the Medicaid Drug Rebate Schedule (Form CMS-64.9R), which is part of the Form CMS-64. CMS reimburses States for the Federal share of Medicaid expenditures reported on the Form CMS-64.

Rebates for Physician-Administered Drugs

The Deficit Reduction Act of 2005 amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To collect rebates for drugs, States submit to the manufacturers the drug utilization data containing NDCs for the drugs. NDCs allow States to identify drugs and the manufacturer to collect drug rebates. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to bill and collect rebates.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)³ requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs 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 drug utilization data reported by MCOs when billing manufacturers for rebates. Physician-administered drugs dispensed to enrollees of MCOs are recorded in MCO drug utilization data.

³ 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), collectively referred to as “ACA.”

The State Agency's Medicaid Drug Rebate Program

In Oregon, the State agency is responsible for billing and collecting Medicaid drug rebates for physician-administered drugs. The State agency contracts with Hewlett Packard Enterprise Services (the contractor) to manage its drug rebate program.⁴ The manufacturers pay the rebates directly to the State agency. The State agency forwards the payment information to the contractor, which posts the information in the State agency's Medicaid Management Information System (MMIS). Since calendar year (CY) 2008, the State agency's MMIS has been able to store NDCs submitted by MCOs. The contractor maintains accounts receivable information and works with manufacturers to resolve any unpaid rebates.

HOW WE CONDUCTED THIS REVIEW

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$1,781,608,392 (\$1,299,427,488 Federal share) in CY 2010, which included expenditures for physician-administered drugs. Our audit covered the State agency's MCO payments and MCO drug utilization data for physician-administered drugs from April through December 2010 (audit period).

Because the State agency's MCO expenditures were not identified by specific type of service, we requested that the State agency's actuarial service unit estimate the amount that the State agency paid MCOs for physician-administered drugs and the amount of rebates not collected.⁵ We reviewed these estimates to determine whether they were reasonable.

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 comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not have NDCs for drug utilization data submitted by MCOs for physician-administered drugs, and the State agency did not bill manufacturers for rebates for these drugs. The State agency estimated that it did not collect rebates of \$3,049,462 (\$1,914,462 Federal share). The State agency did not bill manufacturers for rebates because the

⁴ During 2010, the State agency worked with its contractor to implement the billing of rebates for drugs dispensed through MCOs.

⁵ The actuarial service unit's duties and responsibilities include developing actuarially sound managed-care capitation payment rates for Oregon that meet CMS requirements.

State agency's MMIS did not have an edit during our audit period to ensure that NDCs were present and valid in the MCO drug utilization data for physician-administered drugs.

FEDERAL AND STATE REQUIREMENTS

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 enrollees of MCOs 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 enrollees of MCOs. Essentially, States must secure rebates for drugs dispensed through MCOs and require MCOs to submit NDCs to the States for drugs dispensed to eligible individuals in order for the State to bill for rebates (the Act § 1903(m)(2)(A)).

Federal regulations essentially prohibit Federal reimbursement for physician-administered drugs unless the States submit to manufacturers drug utilization data containing NDCs (42 CFR § 447.520).

Oregon's Medical-Surgical Services Administrative Rule 410-130-0180, dated July 1, 2009, requires both the NDC and Healthcare Common Procedure Coding System (HCPCS) code on all claim forms for drug reimbursement.⁶ Through its information memorandum transmittals, the State agency notified providers to submit NDCs on claims for physician-administered drugs.

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

THE STATE AGENCY DID NOT BILL MANUFACTURERS FOR REBATES FOR PHYSICIAN-ADMINISTERED DRUGS DISPENSED TO ENROLLEES OF MEDICAID MANAGED-CARE ORGANIZATIONS

The State agency did not have NDCs for drug utilization data submitted by MCOs for physician-administered drugs, and the State agency did not bill manufacturers for rebates for these drugs. The State agency estimated that it paid \$11,275,385 (\$7,078,720 Federal share) to MCOs for physician-administered drugs, an estimate we determined to be reasonable. On the basis of this amount, the State agency estimated that it did not collect rebates of \$3,049,462 (\$1,914,462 Federal share), an estimate we also determined to be reasonable.

The State agency did not bill manufacturers for rebates because the State agency's MMIS did not have an edit during our audit period to ensure that NDCs were present and valid in the MCO drug utilization data for physician-administered drugs. The State agency informed us that it implemented NDC edits on July 1, 2011. The State agency also informed us that in

⁶ State agency officials informed us that the Administrative Rule also applied to drug utilization data submitted by MCOs.

December 2012, it retroactively billed for and collected from manufacturers rebates for physician-administered drugs dispensed through MCOs and paid since July 1, 2011. Although State regulations and guidance required MCOs to submit NDCs for physician-administered drugs, the State agency did not ensure that MCOs submitted NDCs.

RECOMMENDATIONS

We recommend that the State agency:

- bill for and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs during our audit period and refund to the Federal Government the estimated \$1,914,462 Federal share,
- bill for and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs from January 1 through June 30, 2011, and refund the Federal share of the rebates collected,
- verify that the NDC edits (implemented on July 1, 2011) ensure that NDCs are present and valid in all drug utilization data, and
- ensure that MCOs submit drug utilization data containing NDCs for physician-administered drugs.

STATE AGENCY COMMENTS

The State agency concurred with all of our recommendations and described corrective actions that it had taken or planned to take. 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
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	August 2014
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	August 2014
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	April 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>	April 2014
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	November 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>	September 2013
<i>States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations</i>	<u>OEI-03-11-00480</u>	September 2012
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	August 2011
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	June 2011
<i>Follow-Up Audit of the Medicaid Drug Rebate Program in Oregon</i>	<u>A-09-07-00052</u>	March 2008
<i>Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-02-00660</u>	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Form CMS-64 and determined that the State agency paid MCOs \$1,781,608,392 (\$1,299,427,488 Federal share) in CY 2010, which included expenditures for physician-administered drugs. Our audit covered the State agency's MCO payments and MCO drug utilization data for physician-administered drugs from April through December 2010.

Because the State agency's MCO expenditures were not identified by specific type of service, we requested that the State agency's actuarial service unit estimate the amount that the State agency paid MCOs for physician-administered drugs and the amount of rebates not collected. We reviewed these estimates to determine whether they were reasonable.

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 Medicaid rebates for physician-administered drugs.

We conducted our audit from July 2013 to October 2014 and performed fieldwork at the State agency office in Salem, Oregon.

METHODOLOGY

To accomplish our objective, we:

- reviewed Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs;
- interviewed CMS officials about the Federal laws, regulations, and guidance governing physician-administered drugs under the Medicaid drug rebate program;
- reviewed State regulations and guidance to providers, including billing instructions for physician-administered drugs;
- reviewed State agency policies and procedures for rebates for physician-administered drugs;
- interviewed State agency and rebate contractor personnel to gain an understanding of the administration of and controls over the Medicaid billing and rebate process for physician-administered drugs;
- obtained from the State agency the MCO drug utilization data for physician-administered drugs paid in CY 2010;
- verified whether NDCs were present in the MCO drug utilization data;

- reviewed the State agency’s Form CMS-64 to identify MCO expenditures;
- obtained from the State agency’s actuarial service unit the estimated amount paid to MCOs for physician-administered drugs and the estimated amount of rebates not collected from April through December 2010;⁷
- reviewed the State agency’s actuarial service unit methodology for calculating these estimates and determined whether the estimates were reasonable;
- reviewed the qualifications of the actuary who made the estimates; 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.

⁷ Effective March 23, 2010, the ACA requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. Because capitation payments are made monthly to MCOs, we found the actuarial service unit’s use of the April through December 2010 period to be acceptable.

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

FEDERAL LAWS

Under the Medicaid program, States may provide coverage for outpatient drugs as an optional service (the Act § 1905(a)(12)). Section 1903(a) of the Act provides for Federal financial participation (Federal share) in State expenditures for these drugs.

The Medicaid drug rebate program, created by the Omnibus Budget Reconciliation Act of 1990 (which added section 1927 to the Act), became effective on January 1, 1991. 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)).

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 prohibit payment unless States collect rebates from manufacturers for drugs dispensed through MCOs. This same section specifies that MCO contracts must require the MCOs to submit to the State the drug utilization by NDCs for drugs dispensed to eligible individuals.

States must collect utilization and coding data necessary to secure rebates for certain physician-administered drugs (the Act § 1927(a)(7)). The utilization data must be submitted using NDCs (the Act § 1927(a)(7)(C)).

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).

STATE REGULATIONS AND GUIDANCE

Oregon's Medical-Surgical Services Administrative Rule 410-130-0180, dated July 1, 2009, states that drug reimbursement is made to practitioners only when the drug is administered by the practitioner in the office, the clinic, or home settings. Both the NDC number and HCPCS code are required on all claim forms.

Oregon's information memorandum transmittal (IM) 06-208 reminds providers of the requirement to include the NDC on all electronic claims for physician-administered drugs. The IM states: "The new [MMIS], scheduled to go online late in 2007, will automatically deny drug claims that don't include the NDC."

Oregon's IM 08-201 states that, effective January 1, 2009, NDCs are required on all drug claims. Before submitting a claim for a physician-administered drug, a provider should verify that the drug has an approved NDC and is eligible for rebates.

Oregon's IM 10-153 requires all contracted managed-care plans to include NDC information for physician-administered drugs. Physician-administered drugs that do not contain NDC information will be denied for correction.

APPENDIX D: STATE AGENCY COMMENTS



OFFICE OF THE DIRECTOR

John A. Kitzhaber, M.D., Governor

Oregon
Health
Authority

500 Summer Street NE
Salem OR 97301
www.oregon.gov/oha

January 21, 2015

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90 -7th Street, Ste 3-650
San Francisco, CA 94103

Oregon Health Authority
Medical Assistant Programs
Response to HHS OIG Draft Audit Report
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations
Report Number: A-09-13-02037

Dear Ms. Ahlstrand:

The Oregon Health Authority (OHA) would like to thank the Office of Inspector General (OIG) for this opportunity to respond to the draft audit report. This response will provide our comments with statements of concurrence or non-concurrence with each recommendation.

OHA Comments:

In order to comply with the constantly changing Federal healthcare laws and programs, as well as State legislative directives, OHA prioritized its Medicaid Management Information System (MMIS) programming resources based up on the monetary impact to the State agency. Oregon has a sincere interest in being good stewards of public expenditures. It is important to provide additional context around the findings stated in the report. Just prior to the audit period, Oregon rolled out a new MMIS system that was expected to be readily configurable to implement much of the invoicing needs around drug rebate. However, the configuration of the system required additional programming that, as stated, needed to be prioritized. Due to competing priorities and projected monetary impacts, OHA had to prioritize programming of these changes behind other higher impact items. As of July 1, 2011 the State agency fully implemented National Drug Code (NDC) edits within MMIS. Furthermore, Oregon was a leader in configuring its MMIS to appropriately invoice for managed care drug utilization starting from March 2010. This invoicing change had a substantial monetary implication to Oregon's invoices to drug manufactures and in turn increased rebate revenue to the State and Federal Government.

The OIG requested the State of Oregon respond to each of the recommendations contained in this report with a statement of concurrence or non-concurrence. The State agency responds as directed below:

OIG Recommendation #1

We recommend that the State agency bill for and collect from manufacturers rebates for physician-administered drugs (PAD) dispensed to enrollees of MCOs during our audit period and refund to the Federal Government the estimated \$1,914,462 Federal share.

State Response to OIG Recommendation #1

We concur with the OIG recommendation that OHA invoice manufacturers for rebates for all single-source and top-20 multi-source physician-administered drugs dispensed to enrollees of MCOs during the audit period of April 2010 through December 2010. OHA, through the work of a contractor, will retroactively invoice all single-source and multi-source Healthcare Common Procedure Codes (HCPCs) that have valid National Drug Codes (NDCs) by the end of 2015. The Federal share of all rebates collected will be remitted to the Federal Government.

We further concur that OHA will refund the Federal share balance of expected rebates (approximately \$1,914,462) that are not invoiced.

OIG Recommendation #2

We recommend that the State agency bill for and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs from January 1 through June 30, 2011, and refund the Federal share of the rebates collected.

State Response to OIG Recommendation #2

We concur with the OIG recommendation that the State agency invoice and collect from manufacturers rebates for physician-administered drugs dispensed to enrollees of MCOs from January 1 through June 30, 2011, and remit the Federal share of the rebates collected.

We implemented a process to retro-invoice the eligible claims identified in this report. The scheduled invoicing of these claims is expected in the latter-half of 2015.

OIG Recommendation #3

We recommend that the State agency verify that the NDC edits (implemented on July 1, 2011) ensure that NDCs are present and valid in all drug utilization data.

State Response to OIG Recommendation #3

We concur with the OIG recommendation that the State agency verify that the NDC edits (implemented on July 1, 2011) are present and valid in all drug utilization data.

This functionality is complete, validated and implemented.

OIG Recommendation #4

We recommend that the State agency ensure that MCOs submit drug utilization data containing NDCs for physician-administered drugs.

Lori Ahlstrand
Regional Inspector General for Audit Services
Page 3

State Response to OIG Recommendation #4

We concur with the OIG recommendation to ensure that MCOs submit drug utilization data containing NDCs for physician-administered drugs. Since July 1, 2011, MCO drug utilization data has been required to contain valid NDCs.

Please feel free to contact Dave Lyda, Chief Audit Officer for the Department of Human Services and Oregon Health Authority at [REDACTED] if you have any questions regarding these responses or require additional information.

Sincerely,

Linda Hammond

Linda Hammond
Interim Chief Operating Officer