

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**KANSAS CORRECTLY INVOICED REBATES
TO MANUFACTURERS FOR MOST
PHYSICIAN-ADMINISTERED DRUGS
DISPENSED TO ENROLLEES OF
MEDICAID MANAGED-CARE
ORGANIZATIONS**

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for Audit Services

August 2016
A-07-15-06060

Office of Inspector General

<http://oig.hhs.gov>

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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

Over 3 years Kansas did not invoice manufacturers for some rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Kansas did not collect \$36,000 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 for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General reviews found that States did not always invoice 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 the State of Kansas correctly claimed Federal Medicaid reimbursement for most physician-administered drugs. However, it did not invoice manufacturers for rebates for some physician-administered drugs. For this audit, we reviewed the Kansas Department of Health and Environment, Division of Health Care Finance (State agency), invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Kansas for the period January 1, 2011, through December 31, 2013.

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing 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 § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States.

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 Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). These expenditures are not identified by specific type or service (such as physician-administered drugs). States must also report drug rebates on the CMS-64 report.

The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on certain physician-administered drugs. To collect rebates for these drugs, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for the covered outpatient 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 invoice 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 Medicaid agency for covered outpatient drugs dispensed to eligible individuals. MCOs maintain data on physician-administered drugs dispensed to enrollees of MCOs (MCO drug utilization data) and report those data to the States. In turn, States must include the MCO drug utilization data when billing manufacturers for rebates.

The State agency is responsible for submitting invoices to manufacturers and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by MCOs, to invoice manufacturers. We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2011, and December 31, 2013.

WHAT WE FOUND

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs, it did not invoice all rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not invoice manufacturers for rebates totaling \$63,491 (\$35,949 Federal share). These errors occurred because the State agency's internal controls did not always ensure that it invoiced manufacturers to collect rebates.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government \$35,949 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers and
- strengthen its internal controls to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with both 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
Physician-Administered Drugs	2
The State Agency’s Medicaid Drug Rebate Program.....	3
How We Conducted This Review.....	3
FINDINGS	3
Federal Requirements and State Agency Guidance.....	3
The State Agency Did Not Invoice Manufacturers for Rebates for Some 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.....	8
C: Federal Requirements and State Agency Guidance Related to Physician-Administered Drugs	10
D: State Agency Comments	12

INTRODUCTION

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.) In one of those reviews, which focused on fee-for-service claims, we found that the State of Kansas correctly claimed Federal Medicaid reimbursement for most physician-administered drugs. However, it did not invoice manufacturers for rebates for some physician-administered drugs. For this audit, we reviewed the Kansas Department of Health and Environment, Division of Health Care Finance (State agency), invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) for the period January 1, 2011, through December 31, 2013.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing 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 that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list 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 the information 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.

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

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

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for invoicing manufacturers for rebates as described in section 1927 of the Act. To invoice for rebates, States capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and 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 received 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 (CMS-64 report). These expenditures are not identified by specific type or 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 CMS-64 report. CMS reimburses States for the Federal share of Medicaid expenditures reported on the CMS-64 report.

Physician-Administered Drugs

Drugs administered by a physician are typically invoiced to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes.³

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on certain physician-administered drugs. To collect rebates for these drugs, States submit to the manufacturers the drug utilization data containing NDCs for the covered outpatient drugs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates 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 invoice and collect rebates.

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)⁴ 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 Medicaid agency for covered outpatient drugs dispensed to eligible

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

⁴ 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), is known as the Affordable Care Act or “ACA.”

individuals. MCOs maintain data on physician-administered drugs dispensed to enrollees of MCOs (MCO drug utilization data) and report those data to the States. In turn, States must include the MCO drug utilization data when billing manufacturers for rebates.

The State Agency's Medicaid Drug Rebate Program

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

HOW WE CONDUCTED THIS REVIEW

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2011, and December 31, 2013. We identified drugs that had not been invoiced by the State agency and calculated the amount of rebates that the State agency would have collected from manufacturers had it invoiced them for the drugs.

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.

FINDINGS

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs, it did not invoice all rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not invoice manufacturers for rebates totaling \$63,491 (\$35,949 Federal share). These errors occurred because the State agency's internal controls did not always ensure that it invoiced manufacturers to collect rebates.

FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

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. Under these requirements, States must collect rebates for drugs dispensed through MCOs and must require MCOs to submit NDCs to the States for drugs dispensed to eligible individuals so that the States can invoice for rebates (the Act § 1903(m)(2)(A)).

Federal regulations prohibit Federal reimbursement for physician-administered drugs for which a State has not required the submission of claims containing the NDCs (42 CFR § 447.520).

The *Kansas Medical Assistance Program Provider Manual*, General Introduction, states: “[The State agency] will send provider notification in the form of bulletins and revised manuals” to communicate program policy change. In addition, in the *Kansas Provider Bulletin*, number 661c, dated May 2006, the State agency notified providers that effective July 1, 2006, the State agency would require providers billing for prescription drug products in an office or outpatient setting using a J-Code or other drug-related HCPCS code to include the NDC.

The *Kansas Provider Bulletin*, number 6118c, dated November 2006, modified the provisions of the *Kansas Provider Bulletin*, number 661c, by changing the effective date of these provisions to January 1, 2007,⁵ in response to provider concerns. In this November 2006 guidance, the State agency said that, “[f]or prescription drug products in an office or outpatient setting using a drug-related HCPCS code,” providers “will be required to submit the NDC(s) making up the HCPCS code being billed.”

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

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

The State agency did not always invoice manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs. The State agency did not collect rebates totaling \$63,491 (\$35,949 Federal share) for physician-administered drug claims for which it did not invoice manufacturers for rebates.

The State agency’s internal controls did not always ensure that it invoiced manufacturers for rebates associated with physician-administered drug claims for drugs dispensed to enrollees of MCOs.

⁵ Even with the postponement of the effective date, the State agency’s requirement that providers include NDCs on all physician-administered drug claims was in effect for our entire audit period.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$35,949 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers and
- strengthen its internal controls to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with both 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>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/16
<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>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/15
<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>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/14

Report Title	Report Number	Date Issued
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-13-06040</u>	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	<u>A-09-12-02079</u>	4/30/14
<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>	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00200</u>	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-12-00059</u>	9/19/13
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the MCOs between January 1, 2011, and December 31, 2013. Our audit covered the State agency's MCO payments and MCO drug utilization data for 176,556 physician-administered drug claims for drugs dispensed to enrollees of MCOs.

Our audit objective did not require an understanding or assessment of the complete internal control structure of the State agency. We limited our internal control review to obtaining an understanding of the State agency's processes for reimbursing physician-administered drug claims and its process for claiming and obtaining Medicaid drug rebates for physician-administered drugs dispensed to enrollees of MCOs.

We conducted our audit work, which included contacting the State agency in Topeka, Kansas, from January 2015 to May 2016.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained claim details from the State agency for all drug claims, including physician-administered drugs, for the period January 1, 2011, through December 31, 2013.
- We identified and removed 176,016 physician-administered drug claims that either had been invoiced or that we identified as not eligible for rebate as part of the drug rebate program.

- We reviewed the remaining 540 drug claims and determined the appropriate unit rebate amounts for the associated physician-administered drugs, then calculated the total rebate amount for drugs that had not been rebated.
- We discussed the results of our review with State agency officials on May 18, 2016.

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 C: FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE 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 that added section 1927 to the Act, became effective on January 1, 1991. Manufacturers must enter into a rebate agreement with the Secretary of Health and Human Services and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008.⁶ Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates on covered outpatient drugs dispensed to individuals enrolled in MCOs if the MCOs are responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) of the Act 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 relevant States the drug utilization data, by NDCs, for drugs dispensed to eligible individuals.

⁶ In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the Food and Drug Administration. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, 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 section 1927(a)(7)(B)(i).

FEDERAL REGULATIONS

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

STATE AGENCY GUIDANCE

The *Kansas Medical Assistance Program Provider Manual*, General Introduction, states: “[The State agency] will send provider notification in the form of bulletins and revised manuals” to communicate program policy change.

The *Kansas Provider Bulletin*, number 661c, dated May 2006, notified providers that effective July 1, 2006, the Kansas Medical Assistance Program (that is, the State’s Medicaid program) would require providers billing for prescription drug products in an office or outpatient setting using a J-Code or other drug-related HCPCS code to include the NDC.

The *Kansas Provider Bulletin*, number 6118c, dated November 2006, modified the provisions of the *Kansas Provider Bulletin*, number 661c, by changing the effective date of these provisions to January 1, 2007, in response to provider concerns. In this November 2006 guidance, the State agency said that, “[f]or prescription drug products in an office or outpatient setting using a drug-related HCPCS code,” providers “will be required to submit the NDC(s) making up the HCPCS code being billed.”

Even with the postponement of the effective date, the State agency’s requirement that providers include NDCs on all physician-administered drug claims was in effect for our entire audit period.

In addition, in the *Kansas Provider Bulletin*, number 7142a, dated December 2007, the State agency notified providers that:

[t]o comply with Centers for Medicare & Medicaid Services (CMS) requirements related to the Deficit Reduction Act, a number of changes involving drug-related HCPCS will become effective with dates of service on and after January 1, 2008. Providers have already been required to submit at least one valid National Drug Code (NDC) for all drug-related HCPCS on non-crossover claims starting January 1, 2007. However, effective with dates of service on and after January 1, 2008, Medicare crossover claims⁷ for beneficiaries with both Medicare and Medicaid will no longer be excluded. In addition, drug-related HCPCS code with submitted NDCs not eligible for drug rebate will be denied.

⁷ The term “crossover claims” refers to claims associated with beneficiaries who are eligible for both Medicare and Medicaid. The majority of these claims are paid by Medicare and then sent to Medicaid for payment toward the Medicare deductible and coinsurance (within Medicaid program limits). In this context, the term “non-crossover claims” refers to claims associated with beneficiaries who are eligible for either Medicare or Medicaid, but not both.

APPENDIX D: STATE AGENCY COMMENTS

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July 11, 2016

Patrick J. Cogley
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Report Number: A-07-15-06060

Dear Mr. Cogley:

The Kansas Department of Health and Environment, Division of Health Care Finance (KHDE/DHCF) appreciates the opportunity to provide this response to the June 2016 draft audit report by the U.S. Department of Health and Human Services, Office of the Inspector General (OIG). KDHE would like to thank the OIG audit team for its professionalism throughout our review of its initial findings and recommendations.

OIG Recommendation 1: Refund to the Federal Government \$35,949 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers

The State concurs with the recommendation and will return the \$35,949 Federal Share for physician-administered drugs dispensed to enrollees of managed care organizations that were not invoiced to manufacturers.

OIG Recommendation 2: Strengthen its internal controls to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced

The State concurs with this recommendation but would like to highlight some of the complexities of implementing the collection of rebates for PADs based on the NDC.

The majority of findings were related to changes in the NDC/HCPCS crosswalk. This crosswalk is used during drug rebate related claims editing and the quarterly invoicing cycle. The main input for the crosswalk is the Noridian monthly file supplemented with manual updates performed by the clinical pharmacy team.

In September of 2013, change order 15218 identified several issues related to the monthly Noridian file and crosswalk update process. These changes were placed into production in September 2014, strengthening the monthly crosswalk

1

update process. However, the OIG MCO PAD audit review encompassed claims spanning January 1, 2011, through December 31, 2013.

Additionally, manual changes to the crosswalk were made by the clinical team while reviewing drug rebate PAD processes from OIGs A-07-14-06056 audit of Fee-for-Service (FFS) PAD Drug Rebate Audit. Both the change order implementation and the manual clean-up of the NDC/HCPDS crosswalk resulted in strengthened controls. Another finding involved one particular single source drug. The drug was identified to be manually added to a drug rebate group but the manual crosswalk update step was missed. A quality check has been added that requires a peer review of the quarterly changes to any drug rebate related HCPDS groups.

Kansas diligently strives to identify and collect all eligible rebates. We will take into consideration OIGs recommendations and identify and implement changes that will improve the identification and collection of PAD rebates.

If you have any questions or comments regarding KDHE's response, please call Jason Osterhaus at (785) 296-2319 or email at josterhaus@kdheks.gov.

Sincerely,

/Christiane Swartz/

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KDHE/DHCF

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