Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

KANSAS CORRECTLY CLAIMED FEDERAL REIMBURSEMENT FOR MOST MEDICAID PHYSICIAN-ADMINISTERED DRUGS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Patrick J. Cogley
Regional Inspector General
for Audit Services

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Office of Inspector General

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EXECUTIVE SUMMARY

Kansas claimed $53,000 over 3 years in Federal reimbursement that was unallowable and $38,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for some physician-administered drugs.

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, recent Office of Inspector General reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians. 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 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.

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 with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. 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 these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered 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 utilization data to invoice and collect rebates.

The State agency is responsible for paying claims, 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 providers, to invoice manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers.

WHAT WE FOUND

Although the State agency generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs, it claimed unallowable Federal

reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with $92,074 ($52,968 Federal share) in physician-administered drugs. Of this amount, $84,636 ($48,661 Federal share) was for single-source drugs, and $7,438 ($4,307 Federal share) was for top-20 multiple-source drugs. Because the State agency did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to collect rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted some claims with NDCs that may have been inaccurate. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that may have had inaccurate NDCs. Furthermore, under applicable Medicaid drug rebate program requirements, the remaining claims, which contained accurate NDCs, could have been eligible for rebates. Accordingly, we set aside $64,800 ($37,585 Federal share) and are recommending that the State agency work with CMS to determine the unallowable portion of the claims that were submitted with potentially inaccurate NDCs and to determine whether the remaining claims could have been invoiced to the manufacturers for rebates.

The State agency notified providers that they were required to include NDCs on all physician-administered drug claims. However, the State agency's internal controls did not always ensure that it invoiced manufacturers for rebates for all eligible physician-administered drugs.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $48,661 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $4,307 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine:

    - the unallowable portion of $37,585 (Federal share) for other claims for outpatient physician-administered drugs, that were submitted with potentially inaccurate NDCs and that may have been ineligible for Federal reimbursement, and refund that amount, and

    - whether the remaining other physician-administered drugs could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; and

- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency concurred with our first, second, and fourth recommendations and described corrective actions that it had taken or planned to take. The State agency did not concur with our third recommendation because certain statutory and regulatory provisions in the criteria did not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs.

After reviewing the State agency's comments, we revised some of the language in our finding regarding other physician-administered drug claims, and in the associated (third) recommendation, to clarify that some of the claims in question had NDCs that may have been inaccurate and to clarify that the remaining claims in question could have been eligible for rebates.

Aside from these clarifications, we maintain that all of our findings and recommendations are valid. We agree with the State agency's comments that certain statutory and regulatory provisions in the criteria specifically address single-source and top-20 multiple-source physician-administered drugs. However, some of the claims that were not invoiced contained Healthcare Common Procedure Coding System codes that, because the claims were submitted with potentially inaccurate NDCs, prevented us from being able to determine the exact drugs that had been dispensed. Furthermore, under applicable Medicaid drug rebate program requirements, all of the claims should have been eligible for rebates; moreover, the drug manufacturers would have been required to pay for the rebates had the State agency invoiced them for the rebates. For these reasons, we revised the language (though not the dollar amount) in our third recommendation. Specifically, we went into greater detail in that recommendation to clarify that if the remaining other physician-administered drugs could have been invoiced to the manufacturers to receive rebates, then for those claims, the State agency should refund the Federal share of the rebates after receiving them from manufacturers. Therefore, we continue to recommend that the State agency work with CMS to determine the unallowable portion of these claims and refund that amount.

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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, recent 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.) 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 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.

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. 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.

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

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

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

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, 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.

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] For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.[4]

The Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs.[5] 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. Before the DRA, many States did not collect rebates on physician-administered drugs if the drug claims did not contain NDCs. NDCs enable States to identify the drugs and their manufacturers and facilitate the collection of rebates for the drugs.

The State Agency's Medicaid Drug Rebate Program

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency also requires providers that are billing for prescription drug products in an office or outpatient setting, using a J-Code or other drug-related HCPCS codes, to include the NDC, the quantity for each submitted NDC, and the unit of measurement for each submitted NDC. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, 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.

[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] As specified in CMS's *Medicare Claims Processing Manual*, chapter 17, section 20.1.2, a single-source drug is a drug for which there is not another therapeutically equivalent drug listed in the most recent Food and Drug Administration (FDA) Orange Book. Multiple-source drugs, by contrast, are drugs for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book.

[5] 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).

HOW WE CONDUCTED THIS REVIEW

The State agency claimed $40,933,108 ($23,580,293 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

We used the CMS Medicaid Drug File to determine whether the NDCs listed on the claims were classified as single-source drugs or multiple-source drugs. For claims in which the State agency determined that the NDC and the HCPCS code did not match, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification.[6] We also used CMS's quarterly Medicaid Drug Rebate Tape to determine whether the NDCs had rebate amounts on the tape. Additionally, we determined whether the HCPCS codes were published in CMS's top-20 multiple-source drug listing.

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, it claimed unallowable Federal reimbursement for some of these drugs. The State agency did not invoice manufacturers for rebates associated with $92,074 ($52,968 Federal share) in physician-administered drugs. Of this amount, $84,636 ($48,661 Federal share) was for single-source drugs, and $7,438 ($4,307 Federal share) was for top-20 multiple-source drugs. Because the State agency did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, the State agency did not submit the utilization data necessary to collect rebates for all other physician-administered drugs. Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted some claims with NDCs that may have been inaccurate. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims that may have had inaccurate NDCs. Furthermore, under applicable

[6] The Medicare Part B crosswalk is published quarterly by CMS and is based on published drug and biological pricing data and information submitted to CMS by manufacturers. It contains the payment amounts that will be used to pay for Part B covered drugs as well as the HCPCS codes associated with those drugs. CMS instructed States that they could use the crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

Medicaid drug rebate program requirements, the remaining claims, which contained accurate NDCs, could have been eligible for rebates. Accordingly, we set aside $64,800 ($37,585 Federal share) and are recommending that the State agency work with CMS to determine the unallowable portion of the claims that were submitted with potentially inaccurate NDCs and to determine whether the remaining claims could have been invoiced to the manufacturers for rebates.

The State agency notified providers that they were required to include NDCs on all physician-administered drug claims. However, the State agency's internal controls did not always ensure that it invoiced manufacturers for rebates for all eligible physician-administered drugs.

FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA 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)). 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)). 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,[7] 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 and State requirements related to physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME SINGLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $84,636 ($48,661 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

[7] 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.

Because the State agency did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON SOME TOP-20 MULTIPLE-SOURCE PHYSICIAN-ADMINISTERED DRUGS

The State agency improperly claimed Federal reimbursement of $7,438 ($4,307 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Before 2012, CMS provided the State agency, on a yearly basis, with a listing of top-20 multiple-source HCPCS codes and their respective NDCs. However, the State agency did not always submit the utilization data to the drug manufacturers for rebate purposes.

Because the State agency did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these top-20 multiple-source physician-administered drugs.

THE STATE AGENCY DID NOT INVOICE MANUFACTURERS FOR REBATES ON OTHER PHYSICIAN-ADMINISTERED DRUGS

We were unable to determine whether the State agency was required to invoice for rebates for an additional $64,800 ($37,585 Federal share) for other physician-administered drug claims.

Although the State agency generally collected the drug utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted some claims with NDCs that may have been inaccurate.[8] Without being able to verify the accuracy of these NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under applicable Medicaid drug rebate program requirements, the remaining claims, which contained accurate NDCs, could have been eligible for rebates. If the State agency would have invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

Accordingly, we set aside the $64,800 ($37,585 Federal share) and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the claims that were submitted with potentially inaccurate NDCs and (2) whether the remaining other physician-administered drugs could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims.

[8] The State agency maintains a HCPCS code/NDC crosswalk and identified some claims that providers had submitted with NDCs that did not match the HCPCS codes specified on those claims. The State agency therefore did not submit these claims for rebates as their NDCs were potentially inaccurate.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $48,661 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;

- refund to the Federal Government $4,307 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine:

    - the unallowable portion of $37,585 (Federal share) for other claims for outpatient physician-administered drugs, that were submitted with potentially inaccurate NDCs and that may have been ineligible for Federal reimbursement, and refund that amount, and

    - whether the remaining other physician-administered drugs could have been invoiced to the manufacturers to receive rebates and, if so, upon receipt of the rebates, refund the Federal share of the manufacturers' rebates for those claims; and

- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred with our first, second, and fourth recommendations and described corrective actions that it had taken or planned to take. The State agency did not concur with our third recommendation because certain statutory and regulatory provisions in the criteria did not specifically address other physician-administered drugs that were not single-source or top-20 multiple-source physician-administered drugs.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we revised some of the language in our finding regarding other physician-administered drug claims, and in the associated (third) recommendation, to clarify that some of the claims in question had NDCs that may have been inaccurate and to clarify that the remaining claims in question could have been eligible for rebates.

Aside from these clarifications, we maintain that all of our findings and recommendations are valid. We agree with the State agency's comments that certain statutory and regulatory provisions in the criteria specifically address single-source and top-20 multiple-source physician-

administered drugs. However, some of the claims that were not invoiced contained HCPCS codes that, because the claims were submitted with potentially inaccurate NDCs, prevented us from being able to determine the exact drugs that had been dispensed. Some of the claims with inaccurate NDCs may have been for single-source drugs. Furthermore, under applicable Medicaid drug rebate program requirements, all of the claims should have been eligible for rebates; moreover, the drug manufacturers would have been required to pay for the rebates had the State agency invoiced them for the rebates. For these reasons, we revised the language (though not the dollar amount) in our third recommendation. Specifically, we went into greater detail in that recommendation to clarify that if the remaining other physician-administered drugs could have been invoiced to the manufacturers to receive rebates, then for those claims, the State agency should refund the Federal share of the rebates after receiving them from manufacturers. Therefore, we continue to recommend that the State agency work with CMS to determine the unallowable portion of these claims and refund that amount.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	07/22/15
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	05/04/15
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	04/13/15
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	03/04/15
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	02/10/15
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	08/21/14
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	08/07/14
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	04/30/14
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	04/24/14
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/13
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	09/19/13
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	08/12/11
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed $40,933,108 ($23,580,293 Federal share) for physician-administered drugs paid between January 1, 2011, and December 31, 2013.

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.

We conducted our audit work, which included contacting the State agency in Topeka, Kansas, from July 2014 to April 2015.

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 listings of the CMS top-20 multiple-source physician-administered drugs, the Medicare Part B crosswalk, the quarterly Medicaid Drug Rebate Tape, and the CMS Medicaid Drug File for our audit period.

- 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 obtained the listing of 340B entities from the State agency.[9]

- We removed drug claims totaling $40,574,374 ($23,373,064 Federal share) that either were not eligible for a drug rebate or contained an NDC and were invoiced for rebate.

- We reviewed the remaining drug claims totaling $358,734 ($207,229 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically:

    - We identified single-source drugs by matching the NDC on the drug claim to the NDC on CMS's Medicaid Drug File. For claims in which the State agency determined that the NDC and the HCPCS code did not match, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify the drug classification (footnote 6).

    - We identified the top 20 multiple-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.

    - We identified other multiple-source drugs by matching the NDC on the drug claim to the NDC on the CMS Medicaid Drug File. For claims in which the State agency determined that the NDC and the HCPCS code did not match, we matched the HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk.

    - We removed drugs totaling $201,860 ($116,676 Federal share) that were not eligible for drug rebates.

- We discussed the results of our review with State agency officials on April 13, 2015.

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.

[9] Under the 340B drug pricing program (set forth in 42 U.S.C. § 256b), a 340B entity may purchase reduced-price covered outpatient drugs from manufacturers; examples of 340B entities are disproportionate share hospitals, which generally serve large numbers of low-income and/or uninsured patients, and State AIDS drug assistance programs. Drugs subject to discounts under the 340B drug pricing program are not subject to rebates under the Medicaid drug rebate program. Section 1927(J) of the Act and 42 U.S.C. § 256b(a)(5)(A).

APPENDIX C: FEDERAL AND STATE 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 (HHS) 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 a 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. 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 1927(a)(7)(D) of the Act allowed HHS to delay any of the above requirements to prevent hardship to States that required additional time to implement the physician-administered drug reporting requirements.

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).

Federal regulations defined a brand-name drug as a single-source or innovator multiple-source drug and, in 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).[10]

STATE AGENCY REQUIREMENTS AND 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 or services 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 claims[11] 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.

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

[11] Office of Inspector General note: 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

Division of Health Care Finance
Landon State Office Building
900 SW Jackson, Suite 900 N
Topeka, Kansas 66612-1220

Kansas

Phone: 785-296-3981
Fax: 785-296-4813
www.kdheks.gov

Susan Mosier, MD, Secretary | Department of Health & Environment | Sam Brownback, Governor

June 30, 2015

Patrick J. Cogley
Regional Inspector General for Audit Services
US Department of Health and Human Services
Office of Audit Services
Region VII
601 East 12th Street
Room 0429
Kansas City, MO 64106

Report Number: A-07-14-06056

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 2015 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 $48,661 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement

KDHE/DHCF concurs with this recommendation. KDHE/DHCF implemented a policy to add these single-source procedure codes to the list of procedure codes Kansas considers physician administered drugs (PADs). Kansas requires the submission of the 837P and 837I NDC loop information when billing for a procedure code in this list if the date of service for the claim detail falls within the effective and end dates on the PAD table. Furthermore, valid NDC to procedure code crosswalks were built so that MMIS editing denies invalid procedure code/NDC combinations based on State policy.

OIG Recommendation 2: Refund to the Federal Government $4,307 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement

KDHE/DHCF concurs with this recommendation. KDHE/DHCF implemented a policy to add these multiple-source procedure codes to the list of procedure codes Kansas considers physician administered drugs (PADs). Kansas requires the submission of the 837P and 837I NDC loop information when billing for a procedure code in this list if the date of service for the claim's detail falls within the effective and end dates on the PAD table. Furthermore, valid NDC to procedure code crosswalks were built so that MMIS editing denies invalid procedure code/NDC combinations based on State policy.

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OIG Recommendation 3: Work with CMS to determine the unallowable portion of the $37,585 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount

KDHE/DHCF does not concur with this recommendation. The Deficit Reduction Act of 2005 (DRA) specifically targeted the collection of rebates for single-source and the top 20 multiple-source PADs. Additionally, CFR 447.520 (b) addresses single-source and the top 20 multiple-source PADs only.

OIG Recommendation 4: Strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced

KDHE/DHCF 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. KDHE/DHCF reviewed the DRA, gathered stakeholders' input, utilized all available guidance and implemented new processes and claims editing to meet the requirements for invoicing the single-source and top 20 multiple-source drugs. KDHE/DHCF also attempted to identify all PAD procedure codes eligible for rebate beyond the single-source and top 20 multiple-source.

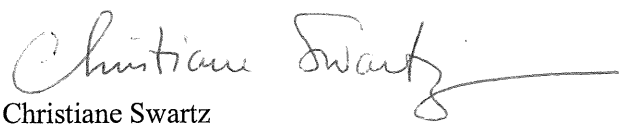
Our implementation of the DRA PAD rebates revolved around the procedure code and whether that code was single or multiple-source. Kansas chose to use this approach due to the following complexities:

- Providers who administer PADs normally administer other services that require the use of procedure codes, such as a Healthcare Common Procedure Coding System (HCPCS) or Current Procedural Terminology (CPTs). Procedure codes are billed on the 837P and 837I electronic transactions or CMS1500/UB04 forms for paper claims. For these providers, the submission of the NDC in addition to all other NDC information resulted in huge changes to billing practices across the country. Even though the 837P and 837I transactions support NDC information in the 2410 loop, providers of PADs were and continue to not be accomplished at submitting the 2410 NDC loop information including the submission of the 2410 loop NDC Unit or Basis of Measurement Code value based on retail pharmacy claim units of measure.
- Kansas is not aware of any list published by the Secretary that identifies every single and multiple-source procedure code. The top 20 multiple-source list was published by the Secretary around 2007/2008. Because a complete list of procedure codes considered PADs was never published, Kansas made a good faith effort to review each code and determine whether or not it should be considered a PAD, thus requiring the submission of the 837P or 837I 2410 NDC loop information.

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
Deputy Medicaid Director
KDHE/DHCF

cc: Michael Randol, Director DHCF
Dr. Susan Mosier, MD, MBA, FACS, KDHE Secretary/ Medicaid Director
Kelley Melton, Pharmacy Director DHCF