

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**INDIANA CLAIMED UNALLOWABLE
FEDERAL REIMBURSEMENT FOR SOME
MEDICAID PHYSICIAN-ADMINISTERED
DRUGS**

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April 2019
A-05-17-00038

Office of Inspector General

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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.

Report in Brief

Date: April 2019

Report No. A-05-17-00038

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



Why OIG 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. However, prior OIG reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether Indiana complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs.

How OIG Did This Review

Our review covered physician-administered drug claims that were paid by Indiana for the period October 1, 2015, through September 30, 2017.

We used the Centers for Medicare & Medicaid Services (CMS) Medicaid Drug File to determine whether each National Drug Code (NDC) listed on the claims was classified as a single-source drug or a multiple-source drug. If the NDC was not listed on the claim, we used CMS's Medicare Part B crosswalk to identify, if possible, the NDC associated with each Healthcare Common Procedure Coding System (HCPCS) code listed on the claims from providers. Additionally, we determined whether the NDC or HCPCS codes were published in CMS's top-20 multiple-source drug listing.

Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs

What OIG Found

Indiana did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Indiana did not invoice manufacturers for rebates associated with \$710,420 (Federal share) in physician-administered drugs. Of this amount, \$695,070 was for single-source drugs, and \$15,350 was for top-20 multiple-source drugs. Because Indiana's internal controls did not always ensure that it invoiced manufacturers to secure rebates, Indiana improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, Indiana did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs totaling \$142,339 (Federal share). Of this amount, \$135,661 was for claims that did not have NDCs and \$6,678 was for claims that contained NDCs.

What OIG Recommends and Indiana Comments

We recommend that Indiana refund \$710,420 and work with CMS to determine the proper resolution of the \$142,339 for the other drug claims in question.

We also made procedural recommendations.

In written comments on our draft report, the State agency partially agreed with our first three recommendations, agreed with our other two recommendations, and described corrective actions that it had taken or planned to take. These corrective actions include a plan to return the Federal share of additional rebate funds as they are received and a description of additional controls that have been or will be implemented to ensure that all eligible claims are invoiced for rebates.

After reviewing the State agency's comments and additional information it provided, we modified some of our findings and the associated recommendations for this final report. We maintain that the remaining findings and recommendations are valid. As of the date we issued our draft report, the reported claims had not been invoiced to the drug manufacturers to secure rebates. Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate.

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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, previous Office of Inspector General (OIG) reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians to fee-for-service enrollees. (Appendix B lists previous OIG reports related to the Medicaid drug rebate program.¹) For this audit, we reviewed the Indiana Family and Social Services Administration's (State agency) invoicing for rebates for physician-administered drugs for the period October 1, 2015, through September 30, 2017 (audit period).

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 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 quarterly. 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, 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

¹ OIG performed similar reviews for rebates due for drugs administered by physicians to enrollees of Medicaid managed-care organizations. These reviews are included in this appendix.

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

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.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, which contains a summary of actual Medicaid expenditures for each quarter and which CMS uses 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 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 physician-administered drug claims to be submitted with the NDC of the product.

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 See, e.g., section 1927(a)(7) of the Act. In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that the U.S. Food & Drug Administration rates as therapeutically equivalent. See, e.g., section 1927(k)(7) of the Act. Single-source drugs do not have therapeutic equivalents.

⁵ The term “top-20 multiple-source drugs” is a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid (the Act § 1927(a)(7)(B)(i)).

The State agency contracted with OptumRX to perform drug rebate processing during our audit period. OptumRX used 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.

HOW WE CONDUCTED THIS REVIEW

Our review covered physician-administered drug claims that were paid by the State agency for the period October 1, 2015, through September 30, 2017.

We used the CMS Medicaid Drug File to determine whether each NDC listed on the claims was classified as a single-source drug or multiple-source drug. If the NDC was not listed on the claim, we used CMS's Medicare Part B crosswalk to identify, if possible, the NDC associated with each HCPCS code listed on the claims from providers.⁶ Additionally, we determined whether the NDC or 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 A contains the details of our audit scope and methodology.

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. The State agency did not invoice manufacturers for rebates associated with \$1,050,235 (\$710,420 Federal share) in physician-administered drugs. Of this amount, \$1,027,426 (\$695,070 Federal share) was for single-source drugs, and \$22,809 (\$15,350 Federal share) was for top-20 multiple-source drugs. Because the State agency's internal controls did not always ensure that it invoiced manufacturers to secure 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 drug utilization data necessary to secure rebates for other physician-administered drugs. Although the State agency generally collected the drug

⁶ CMS publishes the Medicare Part B crosswalk quarterly. It is based on published drug and biological pricing data and information that manufacturers submit to CMS. The crosswalk 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.

utilization data necessary to invoice the manufacturers for rebates associated with these claims, providers submitted claims totaling \$201,525 (\$135,661 Federal share) that did not have NDCs. We were unable to determine whether the State agency was required to invoice for rebates for these other physician-administered drug claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$10,028 (\$6,678 Federal share), which contained NDCs, could have been eligible for 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. 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).

During our audit period, the State agency required providers to submit NDCs along with the procedure code on claims for physician-administered drugs in medical and facility outpatient settings. On July 26, 2016, the State agency issued a bulletin to remind providers to include NDCs when billing for physician-administered drugs.

Appendix C contains Federal requirements and State agency guidance 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 \$1,027,426 (\$695,070 Federal share) for single-source physician-administered drug claims for which it did not invoice manufacturers for rebates.

Because the State agency did not submit utilization data to the manufacturers to secure 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 \$22,809 (\$15,350 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 with an annual 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 secure 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, in some cases, the State agency was required to invoice for rebates 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 other physician-administered drug claims, providers submitted claims, totaling \$201,525 (\$135,661 Federal share), that did not have NDCs. For the claims that did not have NDCs in the utilization data, we were unable to determine whether the State agency improperly claimed Federal reimbursement for the physician-administered drugs associated with these claims. Furthermore, under the Medicaid drug rebate program, claims totaling \$10,028 (\$6,678 Federal share), which contained NDCs, could have been eligible for rebates. If the State agency had invoiced these claims for rebate, the drug manufacturers would have been required to pay the rebates.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$695,070 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$15,350 (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 \$135,661 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount and
 - whether the remaining \$6,678 (Federal share) of other physician-administered drug claims 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;

- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after September 30, 2017; and
- strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency partially agreed with our first three recommendations, agreed with our other two recommendations, and described corrective actions that it had taken or planned to take. These corrective actions include a plan to return the Federal share of additional rebate funds as they are received and a description of additional controls that have been or will be implemented to ensure that all eligible claims are invoiced for rebates.

For our first three recommendations, the State agency provided a breakout of the questioned costs:

- \$669,399 (Federal share). The State agency did not agree with the finding, stating that NDCs for the claims were obtained from the State's Medicaid Management Information System. The State agency said that it will invoice all rebate-eligible claims by August 31, 2019, and provide CMS the Federal share of collected rebates.
- \$117,937 (Federal share). The State agency agreed with the finding, stating that the claims should have been invoiced for rebate. The State agency said that it will work with CMS to determine the amount to be refunded.
- \$65,359 (Federal share). The State agency did not agree with the finding, stating that the claims were invoiced to manufacturers for rebates in February 2019 as a result of our audit. The State agency said that it will provide CMS the Federal share of collected rebates.
- \$64 (Federal share). The State agency agreed with the finding and will work with CMS to determine the amount to be refunded.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments and additional information it provided, we modified some of our findings and the associated recommendations for this final report. Specifically, we removed claims totaling \$3,131 (Federal share) from our draft report's first three recommendations because the State agency provided support that the claims were not covered outpatient physician-administered drug claims eligible for rebates. We maintain that the remaining findings and recommendations are valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the reported claims had not been invoiced to the drug manufacturers to secure rebates. Both Federal requirements and State agency guidance specify that claims for physician-administered drugs must be submitted with NDCs; Federal requirements essentially preclude Federal reimbursement for such claims if they are not invoiced to the manufacturers for rebate.

Although we commend the State agency for the corrective actions it has taken or plans to take, these actions do not relieve the State agency of its responsibility for the claims from our audit period that we questioned. Federal Medicaid requirements related to the collection of rebates for specified categories of physician-administered drugs are well established and provide a basis for disallowance of Federal reimbursement for such claims if they were not invoiced for rebate. However, if the State agency can retrospectively obtain the rebates from the manufacturers and offer to remit the Federal share of the rebates to CMS, then, during the audit resolution process, CMS as the cognizant operating division will decide how to adjust the overpayment amounts conveyed in this report.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered physician-administered drug claims that were paid by the State agency for the period October 1, 2015, through September 30, 2017.

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 performed our fieldwork from September 2017 through October 2018, which included contacting the State agency office in Indianapolis, Indiana.

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 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, and the CMS Medicaid Drug File for our audit period.
- We obtained claim details from the State agency for all physician-administered drugs for the period October 1, 2015, through September 30, 2017.

- We obtained the listing of 340B entities from the State agency.⁷
- We removed drug claims, totaling \$114,968,386 (\$78,909,003 Federal share), that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or were invoiced for rebate.
- We reviewed the remaining drug claims, totaling \$1,261,788 (\$852,759 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 the CMS Medicaid Drug File. If the NDC was not on the drug claim, we identified single-source drugs by matching the HCPCS code on the drug claim to the HCPCS code on CMS’s Medicare Part B crosswalk to identify, if possible, the NDC associated with each HCPCS code listed on claims from providers. We used the CMS Medicaid Drug File to determine whether these NDCs were classified as single-source drugs.
 - We identified the top-20 multiple-source drugs by matching the NDC or HCPCS code on the drug claim to the NDC or HCPCS code on CMS’s top-20 multiple-source drug listing.
 - We identified the remaining drugs (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.
- We discussed the results of our review with State agency officials on September 21, 2018, and November 13, 2018.

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 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 Medicare and Medicaid disproportionate share hospitals, which generally serve large numbers of low-income or uninsured patients, or both, and State AIDS drug-assistance programs.

APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02031</u>	2/16/18
<i>Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-16-00018</u>	2/12/18
<i>Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-13-06046</u>	12/22/17
<i>Texas Did Not Bill Manufacturers for Some Rebates for Pharmacy Drugs of Medicaid Managed-Care Organizations</i>	<u>A-06-16-00004</u>	12/12/17
<i>Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00013</u>	11/01/17
<i>Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02028</u>	9/26/17
<i>Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02029</u>	9/26/17
<i>Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-16-02027</u>	9/12/17
<i>Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations</i>	<u>A-07-16-06065</u>	5/05/17
<i>Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-05-16-00014</u>	3/23/17
<i>Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06050</u>	1/05/17
<i>Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00202</u>	12/30/16

Report Title	Report Number	Date Issued
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-03-15-00201	12/22/16
<i>California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations</i>	A-09-15-02035	12/08/16
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-07-15-06060	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06057	5/26/16
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06063	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-15-06059	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06062	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-15-06058	1/13/16
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-14-02038	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	A-07-14-06056	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06049	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-06-12-00060	5/04/15

Report Title	Report Number	Date Issued
<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
<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 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 the U.S. Department 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 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 States to 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 states 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).

STATE AGENCY GUIDANCE

The State agency's *Provider Reference Module – Injections, Vaccines and Other Physician-Administered Drugs*, effective October 1, 2015, states: "Providers must submit the product National Drug Code (NDC), the NDC unit of measure (UOM), and NDC quantity of units, along with the procedure code, when submitting claims to the IHCP [Indiana Health Coverage Programs] for all physician-administered drugs except for vaccines. This requirement applies to drugs dispensed in professional (medical) and institutional (facility) outpatient settings."

The State agency's *The Indiana Health Coverage Programs Bulletin*, dated July 26, 2016, states: "The Indiana Health Coverage Programs (IHCP) requires providers to report National Drug Codes (NDCs) when billing for physician-administered drugs. This requirement affects all providers who submit paper or electronic claims for drugs administered in professional (medical) and outpatient settings. The NDC requirement also applies to Medicare crossover claims."

APPENDIX D: STATE AGENCY COMMENTS



Eric Holcomb, Governor
State of Indiana

Office of Medicaid Policy and Planning
402 W. WASHINGTON STREET, ROOM W374, MS 07
INDIANAPOLIS, IN 46204-2739

March 4, 2019

Ms. Sheri L. Fulcher
Regional Inspector General for Audit Services
Department Of Health and Human Services
Office of Inspector General
Office of Audit Services, Region V
233 North Michigan Avenue, Suite 1360
Chicago, IL 60601

RE: Report Number A-05-17-00038

Dear Ms. Fulcher:

The Office of Medicaid Policy and Planning (OMPP) of the Indiana Family and Social Services Administration (FSSA) has reviewed the Office of Inspector General (OIG) draft report entitled "Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs". Attached is OMPP's response.

If you have any questions or need additional information, please contact David Nelson at 317-233-3045 and James Shin at 317-234-3635.

Sincerely,

/D. Shane Hatchett for/

Allison Taylor
Indiana Medicaid Director



RECOMMENDATION 1

Refund to the Federal Government \$697,102 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) partially concurs with this recommendation. However, OMPP does not concur with the entire recommendation. A breakout of the \$697,102 Federal share is as follows:

- \$745: OMPP concurs with the finding since the related claims should have been invoiced for Federal rebates, but were not, as a result of claims not containing a National Drug Code (NDC). OMPP will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.
- \$525: OMPP does not concur with the finding since the related claims are for active pharmaceutical ingredient (API) allowable expenditures. APIs are covered by the Medicaid program but not included in the Medicaid Drug Rebate Program. Therefore, rebates are not required for these claims.
- \$58,745: OMPP does not concur with this finding since the related claims were invoiced in February 2019, as a result of the findings within this audit. OMPP will provide the Federal share of the collected rebates to CMS once received from the manufacturers (per requirements of the Medicaid Drug Rebate Program and related CMS64.9R reporting).
- \$635,580: OMPP does not concur with the finding since we have determined that the claims do contain NDCs in the source of record (MMIS). We anticipate all rebate eligible claims will be invoiced by August 31, 2019 so that no Federal funds will need to be refunded to CMS. OMPP will provide the Federal share of the collected rebates when received from the manufacturers (per requirements of the Medicaid Drug Rebate Program and related CMS64.9R reporting).
- \$1,507: OMPP does not concur with the finding since the related claims were determined to be “inpatient” with proper indicators. Since the claims were eligible for Federal share as an inpatient service, the claims are eligible for Federal funding and were reported accordingly within the CMS64 Reports.

RECOMMENDATION 2

Refund to the Federal Government \$15,365 (Federal share) for claims for top-20 multiple source physician-administered drugs that were ineligible for Federal reimbursement.

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) partially concurs with this recommendation. However, OMPP does not concur with the entire recommendation. A breakout of the \$15,365 (Federal share) is as follows:

- \$9: OMPP concurs with the finding since the related claims should have been invoiced for Federal rebates, but were not, as a result of claims not containing a National Drug Code (NDC). OMPP will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.
- \$15,341: OMPP does not concur with the finding since we have determined that the claims do contain NDCs in the source of record (MMIS). We anticipate all rebate eligible claims will be invoiced by August 31, 2019 so that no Federal funds will need to be refunded to CMS. OMPP will provide the Federal share of the collected rebates when received from the manufacturers (per requirements of the Medicaid Drug Rebate Program and CMS64.9R reporting).
- \$15: OMPP does not concur with the finding since the related claims were determined to be “inpatient” with proper indicators. Since the claims were eligible for Federal share as an

inpatient service, the claims are eligible for Federal funding and were reported accordingly within the CMS64 Reports.

RECOMMENDATION 3

Work with CMS to determine

- The unallowable portion of \$136,745 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs and that may have been ineligible for Federal reimbursement and refund that amount.

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) partially concurs with this recommendation. However, OMPP does not concur with the entire recommendation. A breakout of the \$136,745 (Federal share) is as follows:

- \$117,183: OMPP concurs since the related claims should have been invoiced for Federal rebates, but were not, as a result of claims not containing a National Drug Code (NDC). OMPP will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.
- \$18,478: OMPP does not concur with the finding since we have determined that the claims do contain NDCs in the source of record (MMIS). We anticipate all rebate eligible claims will be invoiced by August 31, 2019 so that no Federal funds will need to be refunded to CMS. OMPP will provide the Federal share of the collected rebates when received from the manufacturers (per requirements of the Medicaid Drug Rebate Program and CMS64.9R reporting).
- \$1,084: OMPP does not concur with the finding since the related claims were determined to be “inpatient” with proper indicators. Since the claims were eligible for Federal share as an inpatient service, the claims are eligible for Federal funding and were reported accordingly within the CMS64 Reports.
- Whether the remaining \$6,678 (Federal share) of other physician-administered drug claims 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.

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) partially concurs with this recommendation. However, OMPP does not concur with the entire recommendation. A breakout of the \$6,678 (Federal share) is as follows:

- \$42: OMPP concurs with this finding since the related claims are not eligible for Federal rebate as a result of an incorrect payment of claim (crosswalk of HCPCS code). OMPP will work with CMS to determine whether funds should be refunded based on the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.
- \$22: OMPP concurs with the finding since the related claims are not eligible for Federal rebate as a result of a non-rebating manufacturer (Labeler Code 51927) in the Medicaid

Drug Rebate Program. OMPP will work with CMS to determine timing of the refund of the funds.

- \$6,614: OMPP does not concur with this finding since the related claims were invoiced in February 2019, as a result of the findings within this audit. OMPP will provide the Federal share of the collected rebates to CMS once received from the manufacturers (per requirements of the Medicaid Drug Rebate Program and related CMS64.9R reporting).

RECOMMENDATION 4

Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after September 30, 2017.

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) concurs with this finding and has initiated a project with the rebate vendor to ensure that all rebate eligible claims were invoiced for quarters after September 30, 2017.

RECOMMENDATION 5

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

State Response: The FSSA Office of Medicaid Policy and Planning (OMPP) concurs with this finding and will strengthen controls with all involved vendors (MMIS, enterprise data warehouse, rebate vendor). Included in this activity will be thorough review of current procedures for claims processing requirements (submission of NDCs), data transfers, proper crosswalks and other rebate related operations to ensure that all physician-administered drugs eligible for rebates are invoiced.