

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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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: February 2018

Report No. A-06-16-00018

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

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

How OIG Did This Review

We reviewed claims for physician-administered drugs paid between July 2012 and June 2015.

We used the Centers for Medicare & Medicaid Services' (CMS's) Medicare Part B crosswalk and the CMS Medicaid Drug File to identify single-source and multiple-source drugs. Additionally, we determined whether the Healthcare Common Procedure Coding System codes were published in CMS's top-20 multiple-source drug listing.

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

What OIG Found

Arkansas did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Arkansas did not invoice manufacturers for rebates associated with \$9.9 million (Federal share) in physician-administered drugs. Of this amount, \$8.5 million was for single-source drugs, and \$1.4 million was for top-20 multiple-source drugs. Because Arkansas' internal controls did not always ensure that it invoiced manufacturers to secure rebates, Arkansas improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, Arkansas did not submit the utilization data necessary to secure rebates for all other physician-administered drug claims totaling \$1.4 million (Federal share).

What OIG Recommends and Arkansas Comments

We recommend to Arkansas that it refund \$9.9 million and work with CMS to determine the proper resolution of the \$1.4 million for the other drug claims in question.

We also made procedural recommendations.

In written comments on our draft report, Arkansas concurred with our recommendation to determine the proper resolution of \$1.4 million for other drug claims and concurred with our procedural recommendations. However, Arkansas did not concur that it should refund the Federal share of \$9.9 million in physician-administered drugs that were ineligible for Federal reimbursement because it anticipated that all rebate-eligible drug units would be invoiced "so no Federal funds will need to be refunded to CMS."

After reviewing Arkansas' comments, we maintain that all of our findings and recommendations remain valid. As of the date we issued our draft report, the claims that are included in our findings' amounts 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 the 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, a prior Office of Inspector General review found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix B lists previous reviews of the Medicaid drug rebate program.) For this audit, we reviewed the Arkansas Department of Human Services' (State agency's) invoicing for rebates for physician-administered drugs for the period July 1, 2012, through June 30, 2015.

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 of all covered outpatient drugs to CMS 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, 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

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.

report the information to the manufacturers (the Act § 1927(b)(2)(A)). The number of units is multiplied by the unit rebate amount to determine the actual rebate amount due from each manufacturer.

States report drug rebate accounts receivable data to CMS on the Medicaid Drug Rebate Schedule. This schedule is part of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program report, 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 to 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 all physician-administered drug claims to be submitted with the NDC of the product.

The State agency contracted with Hewlett Packard (HP) to perform drug rebate processing from July 1, 2012, through March 31, 2015, and Magellan Medicaid Administration (Magellan) from

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

⁴ See, e.g., the Act § 1927(a)(7). 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., the Act § 1927(k)(7). Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents.

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 § 1927(a)(7)(B)(i).

April 1, 2015, through June 30, 2015. HP and Magellan 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

The State agency claimed \$86,328,367 (\$60,738,373 Federal share) for physician-administered drugs paid between July 1, 2012, and June 30, 2015.

We used CMS's Medicare Part B crosswalk to identify, if possible, the NDCs associated with each HCPCS code listed on claims from providers. We then used the CMS Medicaid Drug File to determine whether the identified NDCs were classified as single-source drugs or multiple-source drugs.⁶ 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 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 \$14,029,738 (\$9,892,356 Federal share) in physician-administered drugs. Of this amount, \$12,080,550 (\$8,516,758 Federal share) was for single-source drugs, and \$1,949,188 (\$1,375,598 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 utilization data necessary to secure 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 claims totaling \$86,753 (\$61,010 Federal share) that did not have

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.

NDCs or had invalid 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 \$1,969,536 (\$1,388,523 Federal share), which contained NDCs, could have been eligible for rebates. Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$86,753 (\$61,010 Federal share) of claims that were submitted without NDCs or with invalid NDCs and (2) whether the remaining \$1,969,536 (\$1,388,523 Federal share) of claims could have been invoiced to the manufacturers 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).

In an October 2007 policy update to Arkansas Medicaid providers, the State agency stated that to maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected or denied.

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 \$12,080,550 (\$8,516,758 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 \$1,949,188 (\$1,375,598 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 some claims, totaling \$86,753 (\$61,010 Federal share), that did not have NDCs or had invalid NDCs. For the claims that did not have NDCs or had invalid 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 \$1,969,536 (\$1,388,523 Federal share), which contained NDCs, could have been eligible for rebates. These claims related to drugs that were non-top-20 multiple-source physician-administered drugs with NDCs. The State agency's obligation to invoice these claims for rebate is unclear.

Accordingly, we set aside these amounts and are recommending that the State agency work with CMS to determine (1) the unallowable portion of the \$86,753 (\$61,010 Federal share) of the claims that were submitted without NDCs or with invalid NDCs and (2) whether the remaining \$1,969,536 (\$1,388,523 Federal share) of other physician-administered drug claims should 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.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$8,516,758 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement;
- refund to the Federal Government \$1,375,598 (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 \$61,010 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs or with invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and
 - whether the remaining \$1,388,523 (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 June 30, 2015; 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 did not concur with our first two recommendations but concurred with our other three recommendations and described corrective actions it planned to take. For our first two recommendations, the State agency did not concur that it should refund the Federal share of single-source and top-20 claims that were ineligible for Federal reimbursement because it anticipated that all rebate-eligible drug units would be invoiced and the Federal share provided to CMS, "so no Federal funds will need to be refunded to CMS." The State agency added that in the event any rebate-eligible drug units could not be invoiced, it would work with CMS to determine whether funds should be refunded on the basis of the Federal share of the claim reimbursement or the Federal share of the uncollected rebate.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, but as of the date we issued our draft report, the claims that are included in our findings' amounts 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 promised to implement going forward, we note that those planned 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 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

The State agency claimed \$86,328,367 (\$60,738,373 Federal share) for physician-administered drugs paid between July 1, 2012, and June 30, 2015.

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 Little Rock, Arkansas, from February 2016 to August 2017.

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 July 1, 2012, through June 30, 2015.
- We removed drug claims totaling \$70,242,340 (\$49,396,484 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 \$16,086,027 (\$11,341,889 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 HCPCS code on the drug claim to the HCPCS code on CMS's Medicare Part B crosswalk to identify, if possible, the NDCs 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 HCPCS code on the drug claim to the HCPCS code on CMS's top-20 multiple-source drug listing.
 - We identified the remaining drugs (those 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 May 23, 2017.

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: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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
<i>Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-03-15-00201</u>	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>	<u>A-09-15-02035</u>	12/8/16
<i>Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-07-15-06060</u>	8/18/16
<i>Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06057</u>	5/26/16

Report Title	Report Number	Date Issued
<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
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-14-06051	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	A-09-13-02037	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-14-00031	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00205	8/21/14
<i>Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-07-13-06040	8/07/14
<i>Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs</i>	A-09-12-02079	4/30/14
<i>Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	A-09-12-02080	4/24/14
<i>Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	A-03-12-00200	11/26/13
<i>Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	A-06-12-00059	9/19/13

Report Title	Report Number	Date Issued
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	A-06-10-00011	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	OEI-03-09-00410	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 (which 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 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 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).

STATE AGENCY GUIDANCE

The State agency policy update to Arkansas Medicaid providers, dated October 2007, states:

Implementation of the Federal Deficit Reduction Act of 2005, Requiring National Drug Codes (NDC) When Billing Drug Procedure Codes

Effective for claims with dates of service on or after January 1, 2008, Arkansas Medicaid will implement billing protocol per the Federal Deficit Reduction Act of 2005. This official notice will explain changes in policy and billing protocol for providers that submit claims for drug HCPCS codes.

To maintain the integrity of the drug rebate program, it is important that the specific NDC from the package used at the time of the procedure be recorded for billing. HCPCS codes submitted using invalid NDCs or NDCs that were unavailable on the date of service will be rejected/denied.

APPENDIX D: STATE AGENCY COMMENTS



Division of Medical Services

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December 8, 2017

RE: **Report Number: A-06-16-00018**

Ms. Patricia Wheeler
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, TX 75242

Dear Ms. Wheeler:

Enclosed is the Arkansas Department of Human Services, Division of Medical Services' response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled *Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*.

If you have any questions or need additional information, please contact Tami Harlan at 501-682-8292 or at Tami.Harlan@dhs.arkansas.gov.

Sincerely,

A handwritten signature in black ink that reads "Tami Harlan".

Tami Harlan
Deputy Director
Division of Medical Services
700 Main St, 4th Floor, Slot 401
Little Rock, AR 72201
Phone (501) 682-8292

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Arkansas Department of Human Services'
Response to OIG Report Number A-06-16-00018

*Arkansas Claimed Unallowable Federal Reimbursement
for Some Medicaid Physician-Administered Drugs*

Response Summary

Beginning with the passage of the Deficit Reduction Act of 2005 (DRA) that required states to begin collecting rebates on physician-administered drugs, the Arkansas Department of Human Services (DHS) has worked vigorously to develop, monitor, and strengthen system processes and controls to ensure manufacturers are appropriately invoiced for eligible physician-administered drug claims. DHS has complied with requiring providers to submit NDCs for physician-administered drugs. Documentation, including policy and internal edits, was provided during this audit to support the requirements.

DHS recognizes that the OIG audit process is a beneficial practice to assist with identifying additional areas of opportunity for improvement, allowing us to continue strengthening our policies and processes around physician-administered drug claims. DHS will also work with the Centers for Medicare & Medicaid Services (CMS) to determine Federal share amounts that are required to be refunded if applicable.

Detailed responses addressing each of the recommendations outlined in the report are provided below:

1. OIG Recommendation to DHS:

Refund to the Federal Government \$8,516,758 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

DHS Response:

The Department does not concur as we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department intends to invoice for the drug rebates related to these claims to bring the Department into compliance with the Federal requirements for reimbursement for physician-administered drugs. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units cannot be invoiced, the Department 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.

2. OIG Recommendation to DHS:

Refund to the Federal Government \$1,375,598 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement.

DHS Response:

The Department does not concur as we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department intends to invoice for the drug rebates related to these claims to bring the Department into compliance with the Federal requirements for reimbursement for physician-administered drugs. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units cannot be invoiced, the Department 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.

3. OIG Recommendation to DHS:

Work with CMS to determine the unallowable portion of \$61,010 (Federal share) for other claims for covered outpatient physician-administered drugs that were submitted without NDCs or with invalid NDCs and that may have been ineligible for Federal reimbursement and refund that amount, and whether the remaining \$1,388,523 (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.

DHS Response:

The Department concurs and will work with CMS to determine whether these claims include any rebate-eligible drug units and, if so, invoice them for rebates. The Department will provide the Federal share of the collected rebates to CMS. In the event any rebate-eligible drug units are identified but cannot be invoiced the Department will also 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.

4. OIG Recommendation to DHS:

Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after June 30, 2015.

DHS Response:

The Department concurs though we anticipate that all rebate-eligible drug units will be invoiced so no Federal funds will need to be refunded to CMS. The Department will provide the Federal share of the collected rebates to CMS. In the event any identified rebate-eligible drug units cannot be invoiced the Department 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.

5. OIG Recommendation to DHS:

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

DHS Response:

The Department concurs and acknowledges that the OIG audit process is beneficial to help identify key areas of additional opportunity for improvements, which allows us to further strengthen our policies and processes around physician-administered drug claims. The Department plans to review current processes to identify any possible areas of improvement with physician-administered drug claim processing.

With the implementation of a new rebate vendor and Medicaid Management Information System, Arkansas Medicaid has already strengthened its processes for identifying, invoicing, and collecting rebates on rebate-eligible drugs.