

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**IOWA DID NOT INVOICE REBATES
TO MANUFACTURERS FOR
PHYSICIAN-ADMINISTERED DRUGS
OF MEDICAID MANAGED-CARE
ORGANIZATIONS**

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



Gloria L. Jarmon
Deputy Inspector General
for Audit Services

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

For March 2012 through December 2014, Iowa did not invoice manufacturers for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations. As a result, Iowa did not collect over \$400,000 in rebates.

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset their Federal share of these rebates against their Medicaid expenditures. States invoice the manufacturers for rebates to reduce the cost of drugs to the program. However, prior Office of Inspector General reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians. For this audit, we reviewed the Iowa Department of Human Services, Iowa Medicaid Enterprise (State agency), invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Iowa for the period March 1, 2012, through December 31, 2014.

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States.

States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. Physician-administered drugs may be covered by the capitation payment. To claim Federal reimbursement, States report to CMS the capitation payments made to MCOs as MCO expenditures on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program (CMS-64 report). These expenditures are not identified by specific type or service (such as physician-administered drugs). States must also report drug rebates on the CMS-64 report.

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

Effective March 23, 2010, the Patient Protection and Affordable Care Act requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the State Medicaid agency for covered outpatient drugs dispensed to eligible individuals, including physician-administered drugs dispensed in an outpatient setting. MCOs maintain data on physician-administered drugs dispensed to enrollees of MCOs (MCO drug utilization data) and report those data to the States. In turn, States must include the MCO drug utilization data when billing manufacturers for rebates.

The State agency is responsible for submitting invoices to manufacturers and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by MCOs, to invoice manufacturers. We reviewed physician-administered drug claims that were paid by the MCOs between March 1, 2012, and December 31, 2014.

WHAT WE FOUND

Before the start of our audit, the State agency did not invoice rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not invoice manufacturers for rebates totaling \$708,938 (\$401,240 Federal share). These errors occurred because the State agency was still in the process of developing policies and procedures to ensure that it accurately invoiced manufacturers to collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government \$401,240 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers,
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2014, and
- develop and implement policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency partially concurred with our first recommendation, concurred with our other two recommendations, and described corrective actions it had taken or planned to take. For our first recommendation, the State agency concurred with the amount of our recommended refund but added that most of this amount had already been refunded to CMS. The State agency also said that its invoicing for physician-

administered drugs dispensed to enrollees of MCOs began in February 2014 (prior to our November 2015 entrance conference) but was subsequently suspended to ensure accuracy of the MCO-related data. The claims in question were, according to the State agency, later reprocessed.

After reviewing the State agency's comments, we maintain that all of our findings and recommendations remain valid.

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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, prior Office of Inspector General reviews found that States did not always invoice and collect all rebates due for drugs administered by physicians.¹ (Appendix A lists previous reviews of the Medicaid drug rebate program.). For this audit, we reviewed the Iowa Department of Human Services, Iowa Medicaid Enterprise (State agency), invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Iowa for the period March 1, 2012, through December 31, 2014.

OBJECTIVE

Our objective was to determine whether the State agency complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to enrollees of MCOs.

BACKGROUND

Medicaid Drug Rebate Program

The Medicaid drug rebate program became effective in 1991 (the Social Security Act (the Act) § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the drug's manufacturer must enter into a rebate agreement that is administered by the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each have specific functions under the program.

Manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price.² On the basis of this information, CMS calculates a unit rebate amount for each drug and provides the information to the States each quarter. Covered outpatient drugs reported by participating drug manufacturers are listed in the CMS Medicaid Drug File, which identifies drugs with such fields as National Drug Code (NDC), unit type, units per package size, and product name.

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 24, 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.

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

States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. States pay MCOs for each individual receiving services regardless of whether the enrollee received services during the relevant time period (42 CFR § 438.2). Physician-administered drugs may be covered by the capitation payment.

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

Physician-Administered Drugs

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

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

Effective March 23, 2010, the Patient Protection and Affordable Care Act (ACA)⁴ requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the State Medicaid agency for covered outpatient drugs dispensed to eligible individuals, including physician-administered drugs dispensed in an outpatient setting. MCOs maintain data on physician-administered drugs dispensed to enrollees of MCOs (MCO drug utilization data) and report those data to the States. In turn, States must include the MCO drug utilization data when billing manufacturers for rebates.

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

⁴ P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), is known as the Affordable Care Act or “ACA.”

The State Agency's Medicaid Drug Rebate Program

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

HOW WE CONDUCTED THIS REVIEW

We reviewed physician-administered drug claims that were paid by the MCOs between March 1, 2012, and December 31, 2014.⁵ We identified drugs that had not been invoiced by the State agency and calculated the amount of rebates that the State agency would have collected from manufacturers had it invoiced them for the drugs.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix B contains the details of our audit scope and methodology.

FINDINGS

Before the start of our audit, the State agency did not invoice rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not invoice manufacturers for rebates totaling \$708,938 (\$401,240 Federal share). These errors occurred because the State agency was still in the process of developing policies and procedures to ensure that it accurately invoiced manufacturers to collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

FEDERAL REQUIREMENTS AND STATE AGENCY GUIDANCE

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

The ACA amended section 1927 of the Act, effective March 23, 2010, to specifically require manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the

⁵ The original starting date for the scope of the claims we reviewed was January 1, 2011. We shortened that timeframe to reflect the fact that the State agency's contracts with the MCOs did not become effective until March 1, 2012.

MCOs are responsible for coverage of such drugs. To bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

The ACA also amended section 1903 of the Act to specifically address the conditions of Federal reimbursement for covered outpatient drugs dispensed to enrollees of MCOs. Under these requirements, States must collect rebates for drugs dispensed through MCOs and must require MCOs to submit NDCs to the States for drugs dispensed to eligible individuals so that the States can invoice for rebates (the Act § 1903(m)(2)(A)).

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

Iowa Informational Release No. 593, dated March 28, 2007, announced that the State agency would be implementing changes involving the reporting of physician-administered drugs to comply with CMS requirements implemented in response to the DRA. This guidance also states that effective May 1, 2007, all claims for dates of service on or after that date for drug products administered in an office, clinic, or other outpatient setting which are reported with a HCPCS code must also include the corresponding NDC. In addition, only those NDCs that are rebatable will be payable by the State agency.

Iowa Informational Release No. 647, dated October 26, 2007, clarifies the guidance in Informational Release No. 593 and states that providers must also ensure that the NDC of the administered drug is noted in the patient's file. The NDC must match the drug administered and not the number from another manufacturer's product, even if the chemical name is the same.

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

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

Before the start of our audit, the State agency did not invoice manufacturers for any rebates for physician-administered drugs dispensed to enrollees of MCOs. Thus, the State agency did not collect rebates totaling \$708,938 (\$401,240 Federal share) for physician-administered drug claims for which it did not invoice manufacturers for rebates.

According to State agency officials, before and during our audit the State agency was in the process of developing policies and procedures to ensure that it accurately invoiced manufacturers for rebates associated with physician-administered drug claims for drugs dispensed to enrollees of MCOs.

State agency officials told us that the State agency was working toward acquiring the ability to rebate for claims submitted by MCOs, but due to data issues between the MCOs, the State agency, and a third-party vendor, the State agency was not successful in rebating these claims

until after our audit work had begun. State agency officials told us during our fieldwork that the State agency had invoiced for these physician-administered drugs in November 2015, and that those efforts covered claims in our audit period, but we did not verify the receipt of these rebates as part of this review. Accordingly, we continue to recommend the recovery of the entire amount. As part of the audit resolution process after publication of our final report, the State agency will have the opportunity to communicate with CMS on the amounts of the rebates it received from manufacturers.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government \$401,240 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers,
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2014, and
- develop and implement policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency partially concurred with our first recommendation, concurred with our other two recommendations, and described corrective actions it had taken or planned to take. For our first recommendation, the State agency concurred with the amount of our recommended refund but added that most of this amount had already been refunded to CMS. The State agency also said that it began invoicing for physician-administered drugs dispensed to enrollees of MCOs in February 2014 (prior to our November 30, 2015, entrance conference) but, after its post-invoicing quality assurance “identified multiple MCO data issues,” suspended invoicing to ensure accuracy of the MCO-related data. According to the State agency, the claims in question were later reprocessed, to include prior-period adjustments.

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 start of our audit, the claims that are included in our findings (and the associated amounts in our recommended refunds) had not been invoiced to the drug manufacturers to secure rebates. As part of the audit resolution process, the State agency will have the opportunity to show CMS the portion of the \$401,240 (the Federal share conveyed in our first recommendation)

that it already refunded. Once that amount has been verified by CMS, the State agency will be responsible for refunding the remaining balance which, according to the State agency, is currently \$19,177.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<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
<i>Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06063</u>	3/31/16
<i>South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06059</u>	2/09/16
<i>Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06062</u>	1/14/16
<i>North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-15-06058</u>	1/13/16

Report Title	Report Number	Date Issued
<i>California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs</i>	<u>A-09-14-02038</u>	1/07/16
<i>Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06056</u>	9/18/15
<i>Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06049</u>	7/22/15
<i>Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-06-12-00060</u>	5/04/15
<i>Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-07-14-06051</u>	4/13/15
<i>Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations</i>	<u>A-09-13-02037</u>	3/04/15
<i>Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs</i>	<u>A-06-14-00031</u>	2/10/15
<i>The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs</i>	<u>A-03-12-00205</u>	8/21/14
<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

Report Title	Report Number	Date Issued
<i>Nationwide Rollup Report for Medicaid Drug Rebate Collections</i>	<u>A-06-10-00011</u>	8/12/11
<i>States' Collection of Medicaid Rebates for Physician-Administered Drugs</i>	<u>OEI-03-09-00410</u>	6/24/11

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed physician-administered drug claims that were paid by the MCOs between March 1, 2012, and December 31, 2014.⁶ Our audit covered the State agency's MCO payments and MCO drug utilization data for 19,867 physician-administered drug claims for drugs dispensed to enrollees of MCOs.

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

We conducted our audit work, which included contacting the State agency in Des Moines, Iowa, from November 2015 to October 2016.

METHODOLOGY

To accomplish our objective, we took the following steps:

- We reviewed applicable Federal laws, regulations, and guidance pertaining to the Medicaid drug rebate program and physician-administered drugs.
- We interviewed CMS officials about the Federal requirements and guidance governing physician-administered drugs under the Medicaid drug rebate program.
- We reviewed State agency regulations and guidance to providers, including invoicing instructions for physician-administered drugs.
- We reviewed State agency policies and procedures for rebates for physician-administered drugs.
- We interviewed State agency personnel to gain an understanding of the administration of and controls over the Medicaid invoicing and rebate process for physician-administered drugs.
- We obtained claim details from the State agency for all physician-administered drugs dispensed to enrollees of MCOs for the period March 1, 2012, through December 31, 2014 (footnote 6).

⁶ The original starting date for the scope of the claims we reviewed was January 1, 2011. We shortened that timeframe to reflect the fact that the State agency's contracts with the MCOs did not become effective until March 1, 2012.

- We identified and removed 11,626 physician-administered drug claims that had not been eligible for rebate as part of the drug rebate program.
- We reviewed the remaining 8,241 drug claims and determined the appropriate unit rebate amounts for the associated physician-administered drugs, then calculated the total rebate amount for drugs that had not been rebated.
- We discussed the results of our review with State agency officials on September 22, 2016.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX C: FEDERAL 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 and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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

Section 1927(a)(7) of the Act requires that States shall provide for the collection and submission of such utilization data and coding (such as J-codes and NDCs) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates for all single-source physician-administered drugs effective January 1, 2006, and for the top 20 multiple-source drugs effective January 1, 2008.⁷ Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

Section 2501 of the ACA amended section 1927(b)(1)(A) of the Act to require that manufacturers pay rebates on covered outpatient drugs dispensed to individuals enrolled in MCOs if the MCOs are responsible for coverage of such drugs. Section 2501 of the ACA also amended section 1927(b)(2)(A) of the Act to prohibit payment unless States collect rebates from manufacturers for drugs dispensed through MCOs. This same section specifies that MCO contracts must require the MCOs to submit to the relevant States the drug utilization data, by NDCs, for drugs dispensed to eligible individuals.

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., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, the term "top-20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act section 1927(a)(7)(B)(i).

FEDERAL REGULATIONS

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

STATE AGENCY REQUIREMENTS AND GUIDANCE

The State agency publishes bulletins, called Iowa Informational Releases or Iowa Informational Letters, to clarify and explain new and existing programs and policies for providers and other interested parties.

Iowa Informational Release No. 593, dated March 28, 2007, announced that the State agency would be implementing changes involving the reporting of physician-administered drugs to comply with CMS requirements implemented in response to the DRA. This guidance also states:

Effective May 1, 2007, all claims for dates of service on or after May 1, 2007 for drug products administered in an office/clinic or other outpatient setting which are reported with a “J” (or HCPCS) code must also include the corresponding National Drug Code (NDC) number. In addition, only those NDCs that are rebatable will be payable by [the State agency].

The NDC number serves as a universal product identifier for drug products. An NDC is 11 digits and can be located on a drug’s packaging or by contacting the manufacturer. [All emphasis (bolding and underlining) in original.]

Iowa Informational Release No. 647, dated October 26, 2007, clarifies the guidance in Informational Release No. 593 and states:

The NDC requirement states that all claims for drug products administered in an office/clinic or other outpatient setting that are reported with a HCPCS “J” code must also include the corresponding National Drug Code (NDC) number. In addition, only those NDCs that are rebatable will be payable by [the State agency]....

Documentation Standards: providers must ensure that the NDC number of the administered drug is noted in the patient’s file. The NDC must match the drug administered and not the number from another manufacturer’s product, even if the chemical name is the same. [All emphasis (bolding and underlining) in original.]



Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

March 29, 2017

Patrick J. Cogley
Regional Inspector General for Audit Services
HHS-OIG-Office of Audit Services
Region VII
601 East 12th Street, Room 0429
Kansas City, MO 64106

RE: *Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations*, Draft Report, A-07-16-06065

Dear Mr. Cogley:

Enclosed please find comments from the Iowa Department of Human Services (DHS) on the March 2, 2017, draft report concerning Office of Inspector General's (OIG) review of the drug rebate claims processed by DHS.

DHS appreciates the opportunity to respond to the draft report and provide additional comments to be included in the final report. DHS strives to administer the program in compliance with applicable Federal and State law, regulations, and other policies. DHS is committed to working with CMS to resolve the issues identified in this audit review and are appreciative of the hard work your staff has undertaken relative to this audit.

Questions about the enclosed response can be addressed to:

Jody Lane-Molnari
Executive Officer II
Division of Fiscal Management
Iowa Department of Human Services
Hoover State Office Building, 1st Floor SW
1305 East Walnut Street
Des Moines, IA 50319-0114

Email: janemo@dhs.state.ia.us

Phone: 515-281-6027

Sincerely,

/Charles M. Palmer/

Charles M. Palmer
Director

CMP/sp

cc: Dan Bittner, Audit Manager

**IOWA DEPARTMENT OF HUMAN SERVICES
RESPONSE TO OIG DRAFT REPORT:**

**Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs
of Medicaid Managed-Care Organizations,
Draft Report, A-07-16-06065**

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 CMS and pay quarterly rebates to states.

States contract with MCOs to provide specific services to enrolled Medicaid beneficiaries, usually in return for a predetermined periodic payment, known as a capitation payment. Physician-administered drugs may be covered by the capitation payment. To claim Federal reimbursement, states report to CMS the capitation payments made to MCOs as MCO expenditure on the quarterly CMS-64 report. These expenditures are not identified by specific type or service (such as physician-administered drugs). States must also report drug rebates on the CMS-64 report.

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

Effective March 23, 2010, the Patient Protection and Affordable Care Act requires manufacturers to pay rebates on covered outpatient drugs dispensed to enrollees of MCOs if the MCOs are responsible for coverage of such drugs. States typically require MCOs to submit NDCs to the state Medicaid agency for covered outpatient drugs dispensed to eligible individuals. MCOs maintain data on physician-administered drugs dispensed to enrollees of MCOs (MCO drug utilization data) and report those data to the state. In turn, states must include the MCO drug utilization data when billing manufacturers for rebates.

The state agency, the Department of Human Services (DHS), is responsible for submitting invoices to manufacturers and collecting Medicaid drug rebates for physician-administered drugs. DHS uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by MCOs, to invoice manufacturers.

For this audit, the OIG reviewed the DHS physician-administered drug claims that were paid by the MCOs for the period March 1, 2012, through December 31, 2014.

OIG Findings and Recommendations

Before the start of the audit, the State agency did not invoice rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, the State agency did not invoice manufacturers for rebates totaling \$708,938 (\$401,240 Federal share). These errors occurred because the State agency was still in the process of developing policies and procedures to ensure that it accurately invoiced manufacturers to collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

OIG recommends that DHS:

- refund to the Federal Government \$401,240 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers,
- work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2014, and
- develop and implement policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

DHS Response

OIG Recommendation #1 – Refund \$401,240 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers.

DHS partially concurs with this recommendation. While DHS concurs with the \$401,240 Federal share amount, the invoiced claims as reported by DHS to the auditors for which the Federal share has already been provided to Centers for Medicare and Medicaid Services (CMS), represents \$382,063. The outstanding Federal share DHS agrees should be refunded is \$19,177. The DHS appreciates the acceptance of the process refinements during the audit to facilitate an accurate calculation of rebate amounts. Additional detail on the invoicing is provided below.

The draft report indicates that prior to the start of the audit the State agency did not invoice rebate-eligible physician administered drugs (PADs) dispensed to enrollees of MCOs. DHS invoicing for MCO PADs began in February 2014, during the 2013Q4 invoicing cycle; the audit entrance conference was November 30, 2015. Post-invoicing quality assurance identified multiple MCO data issues so invoicing was suspended to ensure accurate MCO data. Following validation for accurate encounter data, MCO PAD claims were reprocessed during 2015Q3 invoicing to include prior quarter adjustments for all quarters back to 2012Q2.

The draft report also indicates DHS reported MCO PAD rebates had been reprocessed during the OIG fieldwork; however, the auditors did not verify the receipt of these rebates as part of the review. Therefore, the report recommends the recovery of the entire amount. DHS provided the auditors with the invoiced amount and was not requested to provide the rebate amount paid in the required auditor report template. Therefore, collections were not captured on this specific report but are captured and reported on the 64.9R reports provided quarterly.

The MCO involved in the audited rebate period is no longer contracted with Iowa Medicaid. The contract was terminated December 31, 2015. With the initiation of three new MCO contracts April 1, 2016, the oversight to proactively collect all necessary PAD encounter data to invoice and collect rebates are identified as part of the response to OIG Recommendation #3. This response provides our comprehensive overall oversight plan to improve PAD rebate under the newly contracted MCOs.

DHS acknowledges that as part of the audit resolution process after publication of the final report, DHS will work with CMS on the amounts of the rebates it received from manufacturers and confirm an appropriate refund amount.

OIG Recommendation #2 – Work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2014.

DHS concurs with this recommendation and will work with CMS to determine the unallowable portion related to claims for outpatient PADs that were ineligible for federal reimbursement outside the audit period from January 1, 2015 through December 31, 2015 specific to the one MCO involved in the audit.

However, DHS anticipates that all rebate-eligible drug units have been invoiced so no Federal funds will need to be refunded to CMS. The Department has provided the Federal share of the collected rebates to CMS. In the event any identified rebate-eligible drug units were not invoiced, the Department will work with CMS to determine the amount of funds that should be refunded based on the Federal share of the uncollected rebate. The MCO drug rebate policy oversight plan with the newly contracted MCOs is noted under the response to OIG Recommendation #3.

OIG Recommendation #3 – Develop and implement policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

DHS concurs with this recommendation and notes that all PADs dispensed to MCO enrollees are invoiced for rebate based on the encounter data provided by the MCOs.

For policy clarification on PAD under fee-for service, it should be noted that in addition to the state guidance noted in the draft report, Iowa Informational Letter No. 803 dated July 8, 2009, announced the State agency was implementing changes to the processing requirements for PADs, based on provider input. Effective with dates of service February 1, 2009, DHS began to enforce the rebatable national drug code (NDC) requirement only for single source and top 20 multi-source drugs rather than on all PADs.

With the initiation of contracts with three new MCOs, the MCOs are contractually obligated to submit all encounter data to DHS for all PAD claims to facilitate drug rebate. DHS has educated the MCOs on all aspects of drug rebate and continues to collaborate to ensure maximum invoicing and collection of drug rebates including but not limited to the following areas:

1. Required PAD data elements for drug rebate including 340B drug claims.
2. Confirmation of enforcement by each MCO of the PAD rebatable NDC requirement.
3. Drug rebate dispute resolution process.
4. Monitoring of quarterly invoices for MCO PAD claims including:
 - a. The percentage of claims invoiced.
 - b. The percentage of rebate to Medicaid reimbursement; and,
 - c. The number of claims excluded from invoicing and reasons for exclusion, with assistance in correcting the issue if applicable.