Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

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

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Deputy Inspector General
for Audit Services

December 2017
A-07-13-06046

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.

Report in Brief
Date: December 2017
Report No. A-07-13-06046

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

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 Nebraska complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs).

How OIG Did This Review

We reviewed physician-administered drug claims that were paid by the MCOs between April 1, 2010, and December 31, 2013. We identified drugs that Nebraska had not invoiced and calculated the amount of rebates that the State would have collected from manufacturers had it invoiced them for the drugs.

What OIG Found

Before the start of our audit, Nebraska did not invoice rebate-eligible physician-administered drugs dispensed to enrollees of MCOs. Specifically, Nebraska did not invoice manufacturers for rebates totaling $1.9 million ($1.1 million Federal share). These errors occurred because Nebraska did not have established policies and procedures in place to ensure that it accurately invoiced manufacturers to collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

What OIG Recommends and Nebraska Comments

We recommend that Nebraska refund to the Federal Government $1.1 million for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers; work with the Centers for Medicare & Medicaid Services (CMS) to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2013; and complete the process of developing and implementing policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

Nebraska disagreed with our first recommendation, concurred with our third recommendation, and, for our second recommendation, said that it would work with CMS to analyze and resolve any discrepancies. For our first recommendation, Nebraska said that historical MCO claims were identified as outstanding rebate-eligible covered outpatient drugs and were subsequently invoiced. Nebraska said that in addition, it took steps to ensure an accurate outstanding balance of rebates due on claims that had not previously been invoiced. Nebraska added that since our audit, it has invoiced for those rebates for drug claims that overlapped with our audit period.

We maintain that all of our findings and recommendations remain valid. We recognize that the drug rebate process is fluid and ongoing, and we commend Nebraska for its corrective actions. When we began our audit work, though, the claims that are included in our findings (and the associated amount in our recommended refund) had not been invoiced to the drug manufacturers to secure rebates. As part of the audit resolution process, Nebraska will have the opportunity to show CMS, the cognizant Federal agency, the portion of the amount conveyed in our first recommendation that it has already refunded.

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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 B lists previous reviews of the Medicaid drug rebate program.). For this audit, we reviewed the Nebraska Department of Health and Human Services (DHHS), Division of Medicaid and Long-Term Care (State agency), invoicing for rebates for physician-administered drugs dispensed to enrollees of Medicaid managed-care organizations (MCOs) in Nebraska for the period April 1, 2010, through December 31, 2013.[2]

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 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.[3] 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

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

[2] Federal requirements related to the dispensing of physician-administered drugs include sections 1927(a) and (b) of the Social Security Act (the Act) and section 2501 of the Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010). The latter Federal legislation, 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."

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

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 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.[4]

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.

[4] 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.

Effective March 23, 2010, the ACA (footnote 2) 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'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 April 1, 2010, and December 31, 2013. We identified drugs that had not been invoiced by the State agency and calculated the amount of rebates that the State agency would have collected from manufacturers had it invoiced them for the drugs.

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

Appendix A 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 $1,869,876 ($1,065,264 Federal share). These errors occurred because the State agency did not have established policies and procedures in place 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 MCOs are responsible for coverage of such drugs. To bill for rebates, States must include information for drugs dispensed to individuals enrolled in MCOs when billing manufacturers for rebates (the Act §§ 1927(b)(1)(A) and (b)(2)(A)).

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

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

The Nebraska DHHS *Finance and Support Manual* states: "The Medicaid division may issue provider bulletins to inform providers of regulation interpretations" (Manual Letter number 59-2003 (revised October 15, 2003), chapter 2-000, "Provider Participation," section 2-001.08 (471 NAC [Nebraska Administrative Code] 2-001.08)).

Through Nebraska Provider Bulletin No. 08-03, dated January 31, 2008, the State agency notified providers that "claims for all physician administered medications will require submission of NDCs." In addition, through Nebraska Provider Bulletin No. 10-31, dated June 30, 2010, the State agency notified providers that "[c]laims submitted for payment that do not meet the NDC reporting requirements to include a valid NDC, quantity, and unit of measurement will result in line item denial."[5]

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

[5] The State agency confirmed to us that its intended audience for Nebraska Provider Bulletin No. 10-31 was fee-for-service providers. The guidance establishing similar controls did not exist for Nebraska Medicaid managed care during the period of this review.

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 $1,869,876 ($1,065,264 Federal share) for physician-administered drug claims for which it did not invoice manufacturers for rebates.

According to State agency officials, during our audit the State agency began 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 during our fieldwork that the State agency had begun to invoice for some of these physician-administered drugs 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 $1,065,264 (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, 2013, and

- complete the process of developing and implementing 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 disagreed with our first recommendation and concurred with our third recommendation and described corrective actions that it had taken or planned to take. For our second recommendation, the State agency said that it would work with CMS "to analyze and resolve any discrepancies uncovered."

For our first recommendation, the State agency said that historical MCO claims were identified as outstanding rebate-eligible covered outpatient drugs and were subsequently invoiced. The State agency said that in addition, it took steps to ensure an accurate outstanding balance of rebates due on claims that had not previously been invoiced. The State agency also stated that since our audit was conducted, the State has developed and strengthened policies and procedures to ensure that it accurately invoices manufacturers for rebates associated with physician-administered drug claims for drugs dispensed to enrollees of MCOs. The State agency added that it has since invoiced for those rebates for drug claims that overlapped with our audit period.

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, and we commend the State agency for the corrective actions it has implemented and plans to implement. When we began our audit work, though, the claims that are included in our findings (and the associated amount in our recommended refund) had not been invoiced to the drug manufacturers to secure rebates. We also recognize that after the start of our audit, the State agency began to invoice some of the claims (those that the State agency's comments referred to as "historical MCO claims") that we identified in our findings. However, there is a significant portion of the claims we identified that the State agency did not invoice for rebate.

Moreover, as part of the audit resolution process, the State agency will have the opportunity to show CMS the portion of the amount conveyed in our first recommendation that it has already refunded. On that basis, 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

We reviewed physician-administered drug claims that were paid by the MCOs between April 1, 2010, and December 31, 2013. Our audit covered the State agency's MCO payments and MCO drug utilization data for 299,700 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 Lincoln, Nebraska, from March 2013 to September 2017. Delays in completion of this audit were caused by a period in which audit staff had to be shifted to higher-priority work and by difficulties in obtaining accurate and complete data from the State agency.

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 April 1, 2010, through December 31, 2013.

- We identified and removed 246,694 physician-administered drug claims that had not been eligible for rebate as part of the drug rebate program.

- We reviewed the remaining 53,006 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 August 14, 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
Ohio Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00013	11/01/17
Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02029	9/26/17
Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02028	9/26/17
Nevada Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-16-02027	9/12/17
Iowa Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs of Medicaid Managed-Care Organizations	A-07-16-06065	5/05/17
Wisconsin Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-05-16-00014	3/23/17
Colorado Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06050	1/05/17
Delaware Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00202	12/30/16
Virginia Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-03-15-00201	12/22/16

Report Title	Report Number	Date Issued
California Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Some Medicaid Managed-Care Organizations	A-09-15-02035	12/8/16
Kansas Correctly Invoiced Rebates to Manufacturers for Most Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-07-15-06060	8/18/16
Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06057	5/26/16
Wyoming Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06063	3/31/16
South Dakota Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-15-06059	2/09/16
Montana Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06062	1/14/16
North Dakota Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-15-06058	1/13/16
California Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-14-02038	1/07/16
Kansas Correctly Claimed Federal Reimbursement for Most Medicaid Physician-Administered Drugs	A-07-14-06056	9/18/15
Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06049	7/22/15
Texas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-06-12-00060	5/04/15
Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-14-06051	4/13/15

Report Title	Report Number	Date Issued
Oregon Did Not Bill Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	A-09-13-02037	3/04/15
Louisiana Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-14-00031	2/10/15
The District of Columbia Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00205	8/21/14
Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-07-13-06040	8/07/14
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	4/30/14
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	4/24/14
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	11/26/13
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	9/19/13
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	8/12/11
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	6/24/11

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.[6] Section 1927(a)(7)(C) of the Act stated that, effective January 1, 2007, the utilization data must be submitted using the NDC. To secure rebates, States are required to report certain information to manufacturers within 60 days after the end of each rebate period (the Act § 1927(b)(2)(A)).

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

[6] In general terms, multiple-source drugs are covered outpatient drugs for which there are two or more drug products that are rated therapeutically equivalent by the Food and Drug Administration. See, e.g., section 1927(k)(7) of the Act. Multiple-source drugs stand in contrast to single-source drugs, which do not have therapeutic equivalents. Further, the term "top-20 multiple-source drugs" is drawn from a CMS classification and describes these drugs in terms of highest dollar volume of physician-administered drugs in Medicaid. The Act section 1927(a)(7)(B)(i).

FEDERAL REGULATIONS

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

STATE AGENCY REQUIREMENTS AND GUIDANCE

The Nebraska DHHS *Finance and Support Manual*, Manual Letter number 59-2003 (revised October 15, 2003), chapter 2-000, "Provider Participation," section 2-001.08 (471 NAC 2-001.08), states: "The Medicaid division may issue provider bulletins to inform providers of regulation interpretations."

Through Nebraska Provider Bulletin No. 08-03, dated January 31, 2008, the State agency notified providers that "claims for all physician administered medications will require submission of NDCs." This guidance also states:

> The Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for physician administered drugs. As a result, states must now collect the 11-digit NDC on all outpatient claims for drugs administered during the course of a patient's clinic visit. Providers are required to submit their claims with the exact NDC that appears on the product administered. The NDC is found on the medication's packaging and must be submitted in the 5digit-4 digit-2 digit format.

In addition, through Nebraska Provider Bulletin No. 10-31, dated June 30, 2010, the State agency notified providers that "[c]laims submitted for payment that do not meet the NDC reporting requirements to include a valid NDC, quantity, and unit of measurement will result in line item denial." (See footnote 5 earlier in this report.)

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

December 20, 2017

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

RE: Report Number: A-07-13-06046 – Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations

Dear Mr. Cogley,

The Nebraska Department of Health and Human Services (DHHS) Division of Medicaid and Long-Term Care appreciates the opportunity to review and respond to the draft report regarding *'Nebraska Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations'*. DHHS strives to administer Medicaid reimbursement in compliance with current Federal and State law, policies, and procedures and is committed to working to resolve the issues identified in this audit review.

This audit period covered April 1, 2010, through December 31, 2013. Since the audit was conducted, the State has since developed and strengthened policies and procedures to ensure that the State accurately invoices manufacturers for rebates associated with physician-administered drug claims for drugs dispensed to enrollees of managed care organizations (MCOs). The State has also since invoiced for those rebates to drug claims that overlap with this audit period.

DHHS' specific responses to each of the preliminary findings and recommendations identified in the Draft Audit Report follow.

1. **OIG Recommendation #1:** Refund to the Federal Government $1,065,264 (Federal share) for rebates for physician-administered drugs dispensed to enrollees of MCOs that were not invoiced to manufacturers.

   DHHS response: The state disagrees. Historical MCO claims were identified as outstanding rebate-eligible covered outpatient drugs and were subsequently invoiced. Conversions were researched and corrected to ensure an accurate outstanding balance of rebate due on claims that had not previously been invoiced. Further disputes by manufacturers related to possible conversion or provider billing errors continue to be investigated and corrected in the rebate process.

2. **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, 2013.

DHHS response: DHHS will work collaboratively with CMS to analyze and resolve any discrepancies uncovered.

3. **OIG Recommendation #3:** Complete the process of developing and implementing policies and procedures to ensure that all physician-administered drugs dispensed to enrollees of MCOs and eligible for rebates are invoiced.

   DHHS response: The state concurs and, since the timeframe of the audit, has implemented policies and procedures to ensure that Nebraska Medicaid invoices all rebate eligible covered outpatient drug claims. The NE Medicaid MMIS system has been updated to evaluate drug claims and MCO encounters on a quarterly basis. Managed Medicaid claim files are received by MMIS. Edits have been placed to extract drug claim data to exclude products that are not rebatable as well as interface with a HCPCS-NDC crosswalk which automate conversions to strengthen the rebate process. The quarterly rebate process works to provide an effective and complaint drug rebate program.

Thank you for the opportunity to respond to this report. If you have any questions regarding our responses please contact me.

Sincerely,

Thomas “Rocky” Thompson, Interim Director
Division of Medicaid and Long-Term Care
Nebraska Department of Health and Human Services

cc: Michael Michalski
Heather Leschinsky
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