Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NEBRASKA CLAIMED UNALLOWABLE FEDERAL REIMBURSEMENT FOR SOME MEDICAID PHYSICIAN-ADMINISTERED DRUGS

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EXECUTIVE SUMMARY

Nebraska claimed $2.5 million over 3 years in Federal reimbursement that was unallowable and $869,000 that may have been unallowable because it did not comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

WHY WE DID THIS REVIEW

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States, and States generally must offset their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, a recent Office of Inspector General review found that States did not always bill and collect all rebates due for drugs administered by physicians.

Our objective was to determine whether the Nebraska Department of Health and Human Services, Division of Medicaid and Long-Term Care (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

The Medicaid drug rebate program became effective in 1991 (the Social Security Act, § 1927). For a covered outpatient drug to be eligible for Federal reimbursement under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to specifically address the collection of rebates on certain physician-administered drugs. To collect these rebates, States submit to the manufacturers the drug utilization data containing National Drug Codes (NDCs) for all single-source physician-administered drugs and for the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing NDCs to bill and collect rebates.

The State agency is responsible for paying claims, submitting invoices to manufacturers, and collecting Medicaid drug rebates for physician-administered drugs. The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to bill manufacturers quarterly and to maintain a record of rebate accounts receivable due from the manufacturers.

WHAT WE FOUND

The State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. The State agency did not collect the NDCs (from claims submitted by providers) that were required for it to invoice manufacturers for rebates associated with $4,114,707 ($2,456,631 Federal share) in physician-administered

drugs. Of this amount, $3,376,414 ($2,015,620 Federal share) was for single-source drugs, and $738,293 ($441,011 Federal share) was for top-20 multiple-source drugs. Because the State agency did not obtain NDC-level detail on the claims and did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

The State agency did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $1,460,514 ($869,291 Federal share) for other physician-administered drug claims that may have included single-source drugs.

The State agency required providers to include NDCs on all physician-administered drug claims, and the State agency notified providers that it would deny claims that did not include NDCs. However, the State agency did not have a system edit in place to reject all of the claims that were submitted without NDCs. As a result, the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with these physician-administered drug claims, and the claims were therefore ineligible for Federal reimbursement.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund to the Federal Government $2,015,620 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $441,011 (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 the $869,291 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount,

- work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after January 1, 2012, and

- update its system edits to require NDCs for payment on all drug claims to ensure that all drugs eligible for drug rebates are invoiced.

STATE AGENCY COMMENTS AND OUR RESPONSE

In written comments on our draft report, the State agency partially agreed with our first two recommendations, disagreed with our third recommendation, and agreed with our fourth and fifth

recommendations. The State agency also described corrective actions that it had taken or planned to take.

The State agency did not agree with the amounts of the refunds that we specified in our first two recommendations. For each of these recommendations, State agency officials said that they would analyze the ineligible claims that we had identified and work with CMS to determine the portion of the Federal share identified in each of our first two recommendations that could not be invoiced and refund those amounts. The State agency disagreed with our third recommendation. State agency officials said that the Federal regulations cited in this report do not require States to invoice drug manufacturers for all outpatient physician-administered drugs.

After reviewing the State agency's comments, we continue to recommend that the State agency refund the amounts (the identified Federal shares) in our first two recommendations because it did not obtain NDC-level detail on the claims and did not provide utilization data to the manufacturers to collect rebates as required for single-source physician-administered drugs and top-20 multiple-source physician-administered drugs. We also maintain that our third recommendation remains valid because the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with other physician-administered drug claims and may have improperly received Federal reimbursement for certain physician-administered drugs.

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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, and States generally must offset their Federal share of these rebates against their Medicaid expenditures. States bill the manufacturers for rebates to reduce the cost of drugs to the program. However, a recent Office of Inspector General review found that States did not always bill and collect all rebates due for drugs administered by physicians.[1] (Appendix A lists previous reviews of the Medicaid drug rebate program.)

OBJECTIVE

Our objective was to determine whether the Nebraska Department of Health and Human Services, Division of Medicaid and Long-Term Care (State agency), complied with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs.

BACKGROUND

Medicaid Drug Rebate Program

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

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

Section 1903(i)(10) of the Act prohibits Federal reimbursement for States that do not capture the information necessary for billing manufacturers for rebates as described in section 1927 of the Act. To bill for rebates, States must capture drug utilization data that identifies, by NDC, the number of units of each drug for which the States reimbursed Medicaid providers and must 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.

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

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

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 billed to the Medicaid program on a claim form using Healthcare Common Procedure Coding System (HCPCS) codes. For purposes of the Medicaid drug rebate program, physician-administered drugs are classified as either single-source or multiple-source.[3]

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.[4] 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 allow States to identify the drug and its manufacturer to collect drug rebates.

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 "… exact NDC that appears on the product administered."[5] The State agency uses its claim utilization data for physician-administered drugs, which it derives from claims submitted by providers, to bill 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 $45,941,955 ($27,191,859 Federal share) for physician-administered drugs paid between January 1, 2009, and December 31, 2011. Of this, we reviewed $5,575,221

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

[4] 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).

[5] *Nebraska Provider Bulletin*, number 08-03, dated January 31, 2008.

($3,325,922 Federal share) that the State agency claimed for physician-administered drugs that were submitted with a HCPCS code but without an NDC.

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

FINDINGS

The State agency did not always comply with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. The State agency did not collect the NDCs (from claims submitted by providers) that were required for it to invoice manufacturers for rebates associated with $4,114,707 ($2,456,631 Federal share) in physician-administered drugs. Of this amount, $3,376,414 ($2,015,620 Federal share) was for single-source drugs, and $738,293 ($441,011 Federal share) was for top-20 multiple-source drugs. Because the State agency did not obtain NDC-level detail on the claims and did not submit utilization data to the manufacturers to collect rebates, the State agency improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

The State agency did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $1,460,514 ($869,291 Federal share) for other physician-administered drug claims that may have included single-source drugs.

The State agency required providers to include NDCs on all physician-administered drug claims, and the State agency notified providers that it would deny claims that did not include NDCs. However, the State agency did not have a system edit in place to reject all of the claims that were submitted without NDCs. As a result, the State agency did not collect the drug utilization data

[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 Medicare Part B crosswalk as a reference because HCPCS codes and NDCs are standardized codes used across health care programs.

necessary to bill the manufacturers for rebates associated with these physician-administered drug claims, and the claims were therefore ineligible for Federal reimbursement.

FEDERAL AND STATE REQUIREMENTS AND STATE AGENCY GUIDANCE

The DRA amended section 1927 of the Act to specifically address the collection of rebates on physician-administered drugs. States must capture NDCs for single-source and top-20 multiple-source drugs (the Act, § 1927(a)(7)). Federal regulations prohibit Federal reimbursement for physician-administered drugs unless the States submit to manufacturers drug utilization data containing the NDCs (42 CFR § 447.520).

The *Nebraska HHS* [Health and Human Services] *Finance and Support Manual* states that "[t]he Medicaid division may issue provider bulletins to inform providers of regulation interpretations."[7] Through the *Nebraska Provider Bulletin*, number 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 the *Nebraska Provider Bulletin*, number 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."

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

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

The State agency improperly claimed Federal reimbursement of $3,376,414 ($2,015,620 Federal share) for single-source physician-administered drug claims for which it did not bill manufacturers for rebates. These claims were submitted without NDCs and, therefore, the State agency did not provide utilization data to the manufacturers to collect the drug rebates.

Because the State agency did not bill for rebates for all single-source physician-administered drugs, these claims were not eligible for Federal reimbursement.

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

The State agency improperly claimed Federal reimbursement of $738,293 ($441,011 Federal share) for top-20 multiple-source physician-administered drug claims for which it did not collect rebates. The claims were submitted without NDCs and, therefore, the State agency did not provide utilization data to the manufacturers to collect rebates.

During our audit period, CMS provided the State agency, on a yearly basis, with a listing of top-20 multiple-source HCPCS codes and their respective NDCs. The State agency said that it had

[7] *Nebraska HHS Finance and Support Manual*, Manual letter number 59-2003 (revised October 15, 2003), 471 Nebraska Administrative Code (NAC) 2-000, chapter 2-000, section 2-001.08.

configured its automated system to automatically reject any top-20 multiple-source drug claims that had been submitted without corresponding NDCs. However, the State agency's system edits did not always reject these claims.

Because the State agency did not bill for rebates for all top-20 multiple-source physician-administered drugs, the claims that were not billed for rebates were not eligible for Federal reimbursement.

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

The State agency did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether the State agency improperly claimed Federal reimbursement for an additional $1,460,514 ($869,291 Federal share) for other physician-administered drug claims that may have included single-source drugs.[8]

The State agency required providers to include NDCs on all physician-administered drug claims. However, the State agency did not have an edit in place to reject all of the claims that were submitted without NDCs. As a result, the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with these claims and was unable to determine whether manufacturers paid rebates for all of the required physician-administered drugs.

Accordingly, we set aside the $1,460,514 ($869,291 Federal share) for CMS's adjudication.

RECOMMENDATIONS

We recommend that the State agency:

- refund to the Federal Government $2,015,620 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement,

- refund to the Federal Government $441,011 (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 the $869,291 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount,

[8] HCPCS codes for drugs that are included in this finding have both single-source and multiple-source NDCs associated with them.

- work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after January 1, 2012, and

- update its system edits to require NDCs for payment on all drug claims to ensure that all drugs eligible for drug rebates are invoiced.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency partially agreed with our first two recommendations, disagreed with our third recommendation, and agreed with our fourth and fifth recommendations. The State agency also described corrective actions that it had taken or planned to take.

Regarding our first and second recommendations, the State agency did not agree with the amounts of the refunds that we specified. For the first recommendation, State agency officials said that they would analyze the ineligible claims that we had identified and invoice the respective drug labelers for claims for which there were unique NDCs. For the second recommendation, State agency officials said that the classifications used were as reported to CMS by drug labelers, and added that they believe that there were "instances of erroneous classification" involving some of the top-20 multiple-source drugs in the associated finding. The officials also stated that they would work with CMS to determine the portion of the Federal share ($2,015,060 for the first recommendation, $441,011 for the second) that could not be invoiced and refund those amounts to the Federal Government on mutually agreed dates.

The State agency disagreed with our third recommendation. State agency officials said that the Federal regulations cited in this report (42 CFR § 447.520) do not require States to invoice drug manufacturers for all outpatient physician-administered drugs.

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 continue to recommend that the State agency refund the amounts (the identified Federal shares) in our first two recommendations. Federal regulations set conditions for States to obtain a Federal share for covered outpatient drugs administered by a physician. These regulations state 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 bill a manufacturer for rebates (42 CFR § 447.520). The State agency did not meet the conditions needed to obtain the Federal share. Specifically, the State agency did not obtain NDC-level detail on the claims and did not provide utilization data to the manufacturers to collect rebates as required for single-source physician-administered drugs and top-20 multiple-source physician-administered drugs.

Further, we disagree with the State agency's assertion that there were "instances of erroneous classification," because for this review we classified physician-administered drugs according to

the Medicaid Drug File and the top-20 multiple-source drug listings published by CMS. (See "How We Conducted This Review" and Appendix B.) Moreover, the decisions as to precise amounts of refunds from the State agency rest with CMS, as the cognizant operating division, when it works with the State agency during the audit resolution process. Accordingly, if the State agency can retrospectively obtain the rebates from the applicable manufacturers and offer to remit the Federal share of the rebates to CMS, during audit resolution CMS will decide how to adjust overpayment amounts.

For our third recommendation, we agree with the State agency's interpretation of the Federal regulations. For this final report, we slightly revised some of the language in the associated finding regarding other physician-administered drug claims to clarify that these claims may have included single-source drugs.[9] Because the State agency did not collect the drug utilization data necessary to bill the manufacturers for rebates associated with these other physician-administered drug claims, it may have improperly received Federal reimbursement for certain physician-administered drugs. We therefore continue to recommend that the State agency work with CMS to determine the unallowable portion of the $869,291 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount.

[9] For example, HCPCS code J1260 (injection, dolasetron mesylate, 10 milligrams; this medication is used to prevent nausea and vomiting associated with chemotherapy) has associated with it a number of NDCs, at least one of which is classified as a single-source drug.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
Idaho Did Not Bill Manufacturers for Rebates for Some Medicaid Physician-Administered Drugs	A-09-12-02079	April 2014
Oregon Claimed Unallowable Federal Medicaid Reimbursement by Not Billing Manufacturers for Rebates for Some Physician-Administered Drugs	A-09-12-02080	April 2014
Maryland Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs	A-03-12-00200	November 2013
Oklahoma Complied With the Federal Medicaid Requirements for Billing Manufacturers for Rebates for Physician-Administered Drugs	A-06-12-00059	September 2013
Nationwide Rollup Report for Medicaid Drug Rebate Collections	A-06-10-00011	August 2011
States' Collection of Medicaid Rebates for Physician-Administered Drugs	OEI-03-09-00410	June 2011
Follow-Up Audit of the Medicaid Drug Rebate Program in Oregon	A-09-07-00052	March 2008
Medicaid Rebates for Physician-Administered Drugs	OEI-03-02-00660	April 2004

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency claimed $45,941,955 ($27,191,859 Federal share) for physician-administered drugs paid between January 1, 2009, and December 31, 2011. Of this, we reviewed $5,575,221 ($3,325,922 Federal share) that the State agency claimed for physician-administered drugs that were submitted with a HCPCS code but without an NDC.

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 visiting and contacting the State agency in Lincoln, Nebraska, from November 2012 through January 2014.

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 billing 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 billing 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 drug claims, including physician-administered drugs, for the period January 1, 2009, through December 31, 2011.

- We obtained a drug listing from the State agency that was used, according to State agency officials, to identify the NDCs of drugs by HCPCS code.

- We obtained the listing of 340B entities from the State agency.[10]

- We removed drug claims totaling $33,303,083 ($19,662,833 Federal share) that either were not eligible for a drug rebate (including the drug claims submitted by 340B entities) or contained an NDC (which according to State agency officials would already have been rebated).

- We also removed drug claims totaling $7,063,651 ($4,203,104 Federal share) that were submitted without an NDC but that had a HCPCS code that matched the State-maintained drug listing. According to State agency officials, the drug listing would have identified the NDCs associated with the drug claims for rebate purposes.

- We reviewed the remaining drug claims totaling $5,575,221 ($3,325,922 Federal share) to determine whether the State agency complied with Federal Medicaid requirements for billing 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 identify whether these NDCs were classified as single-source drugs. (Because there were often multiple NDCs associated with a single HCPCS code, we were not always able to identify the specific NDC that should have been submitted to the drug manufacturer for rebate purposes.)

    - 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 classified the remaining drugs (ones that were not identified as single-source or as top-20 multiple-source drugs) as other outpatient physician-administered drugs.

- We selected a judgmental sample of five drug claims and the claims related to five NDCs to test the billing and collection of rebates by reviewing copies of rebate invoices submitted to the manufacturers and the resulting remittances.

- We discussed the results of our review with State agency officials on January 8, 2014.

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

[10] A 340B entity receives reduced-price outpatient drugs from manufacturers; examples of 340B entities are State AIDS drug assistance programs and Medicare/Medicaid disproportionate share hospitals.

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 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 U.S. Department of Health and Human Services (HHS) and pay rebates for States to receive Federal funding for the manufacturer's covered outpatient drugs dispensed to Medicaid patients (the Act, § 1927(a)). Responsibility for the drug rebate program is shared among the drug manufacturers, CMS, and the States.

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

Section 1927(a)(7) of the Act requires that States capture utilization and coding data necessary 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.

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 specifically state 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 bill a manufacturer for rebates (42 CFR § 447.520).

Federal regulations in effect during most of the audit period defined a brand-name drug as a single-source or innovator multiple-source drug and, in relevant part, a multiple-source drug as a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent (42 CFR § 447.502).[11]

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

STATE REGULATIONS AND GUIDANCE

The *Nebraska HHS Finance and Support Manual*, Manual letter number 59-2003 (revised October 15, 2003), 471 NAC 2-000, chapter 2-000, section 2-001.08, states that "[t]he Medicaid division may issue provider bulletins to inform providers of regulation interpretations." Through the *Nebraska Provider Bulletin,* number 08-03, dated January 31, 2008, the State agency notified providers that:

> [t]he 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 5 digit-4 digit-2 digit format.

In addition, through the *Nebraska Provider Bulletin*, number 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."

APPENDIX D: STATE AGENCY COMMENTS

Department of Health & Human Services
DHHS
NEBRASKA

Division of Medicaid and Long-Term Care

State of Nebraska
Dave Heineman, Governor

May 21, 2014

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

RE: Report Number: A-07-13-06040

Dear Mr. Cogley:

The Nebraska Department of Health and Human Services (DHHS) Division of Medicaid and Long-Term Care is pleased to have the opportunity to respond to the Draft Audit Report entitled *Nebraska Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs.* 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.

DHHS is also appreciative of the hard work on the part of the OIG staff to gather information from staff. Your observations are important in helping improve policies and procedures already in place and ensure continued compliance. DHHS' specific responses to each of the preliminary findings and recommendations identified in the Draft Audit Report follow.

OIG Recommendation #1: We recommend that the State agency refund to the Federal Government $2,015,620 (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement.

DHHS response: DHHS will analyze ineligible claims identified by OIG to classify those claims for which there is a unique National Drug Code (NDC), will invoice the respective drug labelers for rebates. DHHS will work with CMS to determine the portion of the $2,015,620 that is unable to be invoiced and refund that amount to the Federal government on a mutually agreed date. DHHS anticipates incorporating the identified claims into a 2015 rebate cycle. This cycle will include claims identified in subsequent recommendations. DHHS wants to perform one rebate cycle with historical claims to minimize impact for labelers. DHHS will work collaboratively with CMS on project status and refund payment when work is completed.

OIG Recommendation #2: We recommend that the State agency refund to the Federal Government $441,011 (Federal share) for claims for Top-20 multiple- source physician-administered drugs that were ineligible for Federal reimbursement.

DHHS response: DHHS will analyze claims identified by OIG and work collaboratively with CMS to resolve discrepancies uncovered. As discussed with OIG auditors, the classification used was as reported by labelers to CMS. DHHS presented instances of erroneous classification and were instructed to work with CMS directly on resolution. DHHS will refund the portion of the $441,001 (Federal share) for claims for Top-20 multiple-source physician-administered drugs this amount to the Federal government on a mutually agreed date. DHHS has implemented system edits described in a subsequent recommendation to ensure claims are submitted for rebate and eligible for Federal reimbursement.

OIG Recommendation #3: We recommend that the State agency work with CMS to determine the unallowable portion of the $868,291 (Federal share) for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount.

DHHS response: DHHS does not agree with this finding as current regulations (see below) do not require submission of all outpatient physician-administered drugs.

§447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP 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 bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

OIG Recommendation #4: We recommend that the State agency work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claims without NDCs and not billed for rebated after January 1, 2012.

DHHS response: DHHS agrees with the recommendation. The Department is currently working on a Medicaid Drug Rebate data quality project. The Department will gather and analyze data for claims paid after January 1, 2012 and subsequently bill for rebate identified claims not previously invoiced. Once the analysis and invoicing is complete we will work with CMS to determine any unallowable Federal reimbursement for physician-administered drugs claimed without NDCs after January 1, 2012, and refund accordingly.

OIG Recommendation #5: We recommend that the State agency update its system edits to require NDCs for payment on all drug claims to ensure that all drugs eligible for drug rebates are invoiced.

DHHS response: DHHS agrees and has implemented system edits and plans to continue to build and enhance current system edits. DHHS is committed to ensure all drugs eligible for drug rebates are invoiced. As discussed with the OIG auditors, several system edits were implemented during the timeframe of the audit while others are currently being developed. The following list provides further detail to DHHS system edits enacted:

1) In September 2010, MMIS system edits were implemented to deny claims based on; NDC missing or invalid, NDC not effective on claim date of service, NDC rebate status on claim date of service, NDC not valid for Healthcare Common Procedure Coding System (HCPCS) (based on CMS crosswalk) on claim date of service, NDC submitted with generic HCPCS where specific HCPCS (based on CMS crosswalk) is assigned on claim date of service, NDC units qualifier missing or invalid and NDC units missing or invalid.
2) In August 2011, MMIS system edits were implemented to identify claims with NDC unit errors at time of rebate submission and subsequently adjust and recoup payment for claims with submission errors.
3) In May 2012, MMIS system edits were updated to reapply NDC system edits on claim adjustments.
4) In June 2013, MMIS system edits were implemented on NDC submitted units to prevent provider billing discrepancies between NDC units and HCPCS units.
5) In February 2014, DHHS submitted an APD outlining planned MMIS system edits to enhance and strengthen MMIS claims processing. Work is currently underway for a phased implementation of further system edits beginning in December 2014 and scheduled releases in 2015.

If you have any questions regarding our responses or corrective action plans, please contact me at 402-471-9185 or courtney.miller@nebraska.gov.

Sincerely,

Courtney Miller
Deputy Director, Programs
Division of Medicaid and Long-Term Care
Department of Health and Human Services